

DEPARTMENT OF PUBLIC HEALTH

NOTICE OF PROPOSED AMENDMENTS

- 1) Heading of the Part: HIV/AIDS Confidentiality and Testing Code
- 2) Code Citation: 77 Ill. Adm. Code 697
- 3)

<u>Section Numbers:</u>	<u>Proposed Action:</u>
697.10	Repeal
697.20	Amend
697.30	Amend
697.40	Amend
697.100	Amend
697.110	Amend
697.120	Amend
697.130	Amend
697.140	Amend
697.155	New
697.160	Amend
697.170	Amend
697.180	Amend
697.200	Amend
697.210	Amend
697.220	Amend
697.300	Repeal
697.400	Amend
697.410	Repeal
697.420	Amend
697.APPENDIX A ILLUSTRATION A	Repeal
697.APPENDIX C	Repeal
- 4) Statutory Authority: Implementing and authorized by the AIDS Confidentiality Act [410 ILCS 305]
- 5) A Complete Description of the Subjects and Issues Involved: The HIV/AIDS Confidentiality and Testing Code will be updated and revised to correspond to new Centers for Disease Control and Prevention (CDC) standards/guidelines, new laboratory testing methodologies approved by the Food and Drug Administration (FDA), and new Illinois legislation. Archaic tests are being replaced.

Examples of the revisions include: 697.30 (Incorporated Materials) cited guidelines and standards that have been replaced by current CDC recommendations; 697.20

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(Definitions) has references to outmoded laboratory tests that have been replaced by other technologies with improved sensitivity and specificity; 697.120 (Informed Consent) Illinois legislation no longer requires separate written informed consent for HIV testing. Public Act 96-7 amended the AIDS Confidentiality Act to state that informed consent may be written or verbal.

Section 697.300 is being repealed, since HIV Counseling and Testing Centers are obsolete. The Centers for Disease Control and Prevention recommend universal HIV testing for anyone 13 to 64 years of age. Therefore, HIV testing is occurring in doctor's offices, emergency rooms and local health department clinics. Early in the HIV epidemic the Department established special HIV Counseling and Testing Centers where residents could be tested anonymously. However, today the recommendation is to test everyone for HIV at least annually in a variety of clinic settings. Section 697.300, which was advisory, is being repealed.

The appendices are being repealed, since written informed consent is no longer required. (See Section 197.120.)

The economic effect of this proposed rulemaking is unknown. Therefore, the Department requests any information that would assist in calculating this effect.

The Department anticipates adoption of this rulemaking approximately six to nine months after publication of the Notice in the *Illinois Register*.

- 6) Published studies or reports, and sources of underlying data, used to compose this rulemaking: 2008 Revised Surveillance Case Definitions for HIV Infection Among Adults, Adolescents, and Children Aged Less than 18 Months and for HIV Infection and AIDS Among Children Aged 18 Months to 13 Years – United States, 2008, Centers for Disease Control and Prevention (CDC), Morbidity and Mortality Weekly Report (MMWR), December 5, 2008, Vol. 57, No. RR-10; 1-8.

Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health-Care Settings (Centers for Disease Control and Prevention, Morbidity and Mortality Weekly Report (MMWR). MMWR September 22, 2006, Vol. 55, No. RR-14).

- 7) Will this rulemaking replace any emergency rulemaking currently in effect? No
- 8) Does this rulemaking contain an automatic repeal date? No

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- 9) Does this rulemaking contain incorporations by reference? Yes
- 10) Are there any other proposed rulemakings pending on this Part? No
- 11) Statement of Statewide Policy Objectives: This rulemaking does not create or expand any State mandate on units of local government.
- 12) Time, Place and Manner in which interested persons may comment on this proposed rulemaking: Written or e-mail comments may be submitted within 45 days after this issue of the *Illinois Register* to:
- Susan Meister
Division of Legal Services
Illinois Department of Public Health
535 W. Jefferson St., 5th floor
Springfield, Illinois 62761
- 217/782-2043
e-mail: dph.rules@illinois.gov
- 13) Initial Regulatory Flexibility Analysis:
- A) Types of small businesses, small municipalities and not for profit corporations affected: Health care professionals, health care providers and health care facilities as defined in the rules.
- B) Reporting, bookkeeping or other procedures required for compliance: Reporting requirements are set forth in the rules.
- C) Types of professional skills necessary for compliance: Health care professionals as defined in the rules.
- 14) Regulatory Agenda on which this rulemaking was summarized: January 2011

The full text of the Proposed Amendments begins on the next page:

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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

SUBPART A: GENERAL PROVISIONS

Section

- | 697.10 Applicability ~~(Repealed)~~
- 697.20 Definitions
- | 697.30 Incorporated ~~and Referenced~~ Materials
- 697.40 Administrative Hearings

SUBPART B: HIV TESTING

Section

- 697.100 Approved HIV Tests and Testing Procedures
- 697.110 HIV Pre-Test Information
- | 697.120 ~~Written~~-Informed Consent
- 697.130 Anonymous Testing
- 697.140 Nondisclosure of the Identity of a Person Tested or Test Results
- 697.150 Marriage License Testing Requirements (Repealed)
- | 697.155 Delivery of HIV Text Results
- 697.160 HIV Testing for Insurance Purposes
- 697.170 Enforcement of the AIDS Confidentiality Act
- 697.180 HIV Testing for Blood and Human Tissue Donations

SUBPART C: HIV/AIDS REGISTRY SYSTEM

Section

- 697.200 HIV/AIDS Registry System
- 697.210 Reporting Requirements
- | 697.220 Release of HIV/AIDS Registry ~~Data~~Information

SUBPART D: HIV COUNSELING AND TESTING CENTERS

Section

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697.300 HIV Counseling and Testing Centers (Repealed)

SUBPART E: MISCELLANEOUS PROVISIONS

Section

697.400 Notification of School Principals
 697.410 Guidelines for the Management of Chronic Infectious Diseases in School
 Children (Repealed)
 697.420 Testing, Treatment or Counseling of Minors

697.APPENDIX A Sample HIV Testing Forms (Repealed)
 697.ILLUSTRATION A Sample Written Informed Consent for HIV Antibody
 Testing (Repealed)
 697.ILLUSTRATION B Sample Marriage License Testing Certificate (Repealed)
 697.APPENDIX B Statutory and Regulatory References to AIDS (Repealed)
 697.APPENDIX C Sample Written Informed Consent for Rapid HIV Antibody Testing
(Repealed)

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 January 20, 1995; amended at 22 Ill. Reg. 21994, effective December 9, 1998; amended at 28 Ill. Reg. 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. _____, effective _____.

SUBPART A: GENERAL PROVISIONS

Section 697.10 Applicability (Repealed)

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- a) ~~This Part is in response to various statutes concerning acquired immunodeficiency syndrome (AIDS). The provisions of this rulemaking are organized into six components which consist of five Subparts and one appendix. Subpart A includes general provisions which apply to all Sections of the Part such as definitions and administrative hearing rules.~~
- b) ~~Subpart B includes provisions concerning testing for the presence of antibodies to the human immunodeficiency virus (HIV) or any other causative agent of acquired immunodeficiency syndrome (AIDS). These provisions set forth the approved HIV tests and testing procedures, the information that must be given by a physician prior to ordering a HIV test, the written informed consent a physician must obtain prior to performing a HIV test, the requirements for HIV testing for insurance purposes, testing requirements for blood and human tissue donations, the disclosure or confidentiality rules, and the rules for enforcement of the AIDS Confidentiality Act.~~
- c) ~~Subpart C includes the provisions for the implementation of the HIV/AIDS Registry System. These provisions include information reported and the entities which report. In addition, provisions concerning the disclosure of registry information are included.~~
- d) ~~Subpart D includes provisions for the establishment and operation of alternative test sites known as "HIV Counseling and Testing Centers." These provisions specify how the centers are to be used and include a brief outline of the services to be provided.~~
- e) ~~Subpart E includes miscellaneous provisions which concern children. These provisions set forth the requirements for notification of school principals of children with AIDS and HIV infection, the guidelines for management of chronic infectious diseases in school children, and requirements for testing, treatment or counseling of minors.~~
- f) ~~The appendix includes a written informed consent form.~~

(Source: Amended at 36 Ill. Reg. _____, effective _____)

Section 697.20 Definitions

~~The following are definitions of terms used in this Part:~~

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"Act" or "~~AIDS Confidentiality Act~~" means the AIDS Confidentiality Act ~~[410 ILCS 305]~~.

~~"AIDS" means acquired immunodeficiency syndrome (Section 3(b) of the Act), as defined by the Centers for Disease Control or the National Institutes of Health. (Section 3(a) of the AIDS Registry Act) Similar definitions appear in the Act. Current definition can be found in 1993 Revised Classification System for HIV Infection and Expanded Surveillance Case Definition for AIDS Among Adolescents and Adults, Centers for Disease Control and Prevention (CDC). Morbidity and Mortality Weekly Report (MMWR), December 18, 1992; vol. 41, no. RR-17; and in 1994 Revised Classification System for HIV Infection for Children Less Than 13 Years of Age. Morbidity and Mortality Weekly Report (MMWR), vol. 43 RR-12.~~

"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 AgentAgency" means an organization designated by the Department to conduct public health activities in accordance with a written service agreement with the Department. a health care organization under a service agreement with the Department to function in the capacity of a Local Health Authority for the purposes of this Part, in a jurisdiction not covered by a Local Health Authority.~~

"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:

a licensed physician;

a physician assistant to whom the physician assistant's supervising

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physician has delegated the provision of health services;

an advanced practice registered nurse who has a written collaborative agreement with a collaborating physician which authorizes the provision of health services;

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)

"Health Facility" means a hospital, nursing home, blood bank, blood center, sperm bank, or other health care institution, including any "Health Facility" as that term is defined in the Illinois Finance Authority Act [20 ILCS 3501]. (Section 3(e) 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" ~~or "Mortality"~~ means infected with HIV, as evidenced by a positive or reactive supplemental confirmed laboratory test result. for antibodies to HIV as specified in Section 697.100, viral culture or positive antigen test or a clinical diagnosis of AIDS.

"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 ~~any facility or location, other than blood banks,~~ at which tests are performed to determine the presence of a sexually transmitted infection (STI). ~~antibodies to HIV.~~

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"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 provider~~) as determined by the health care ~~professional provider~~ seeking ~~the such~~ 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 AIDS Confidentiality Act [410 ILCS 305/9(k)]~~ 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 [410 ILCS 210/4 and 5]~~ regarding release of test results involving a sexually transmitted ~~infection disease~~,

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,

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Legal guardian or other court-appointed personal representative,

Spouse,

Person in a civil union,

Adult children,

Parent,

Adult next-of-kin.

"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 ~~[410 ILCS 325]~~)

~~"Person" includes any natural person, partnership, association, joint venture, trust, governmental entity, public or private corporation, health facility or other legal entity. (Section 3(h) of the 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 ~~[225 ILCS 60]~~.

"Rapid HIV ~~Antibody~~ 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 ~~a federal Food and Drug Administration (FDA) approved screening test to detect antibodies to HIV~~ that can be collected and processed within ~~a short interval of time (under 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

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~~confirm a positive result for antibody or antigen to HIV virus approved by the FDA for use as a screening or diagnostic test.~~

~~"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 for antibody or antigen to HIV virus approved by the FDA for use as a supplemental or confirmatory test.~~

~~"Test" or "HIV Test" means a test to determine the presence of the antibody or antigen to HIV, or of HIV infection. (Section 3(g) of the Act)~~

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

~~"Written Informed Consent" means an agreement in writing executed by the subject of a test or the subject's legally authorized representative without undue inducement such as any element of force, fraud, deceit, duress or other form of constraint or coercion (See Appendix A, Illustration A), which entails at least the following:~~

~~A fair explanation of the test, including its purpose, potential uses, limitations and the meaning of its results; and~~

~~A fair explanation of the procedures to be followed, including the voluntary nature of the test, the right to withdraw consent to the testing process at any time prior to the completion of the laboratory tests, the right to anonymity to the extent provided by law with respect to participation in the test and disclosure of test results, and the right to confidential treatment of information identifying the subject of the test and the results of the test, to the extent provided by law. (Section 3(d) of the Act)~~

(Source: Amended at 36 Ill. Reg. _____, effective _____)

Section 697.30 Incorporated and Referenced Materials

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a) The following materials are ~~incorporated or~~ referenced in this Part:

~~1)a)~~ Illinois Statutes

~~A)1)~~ AIDS Confidentiality Act [410 ILCS 305];

~~B)2)~~ AIDS Registry Act [410 ILCS 310];

~~C)3)~~ ~~The~~ Communicable Disease Prevention Act [410 ILCS 315];

~~D)4)~~ ~~The~~ Unified Code of Corrections [730 ILCS 5];

~~E)5)~~ ~~The~~ Medical Patient Rights Act [410 ILCS 50];

F) Perinatal HIV Prevention Act [410 ILCS 335]

~~G)6)~~ ~~The~~ 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]

J) Illinois Insurance Code [215 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]

O) Criminal Code of 1961 [720 ILCS 5]

P) Code of Civil Procedure [735 ILCS 5]

Q) Illinois Anatomical Gift Act [755 ILCS 50]

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R) Organ Donation Request Act [755 ILCS 60]

S) Communicable Disease Prevention Act [410 ILCS 315]

2)b) Illinois Rules

A)1) Control of Communicable Disease Code (77 Ill. Adm. Code 690) (see in particular Section 697.140(a)(4) of this Part);

B)2) 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)3) Illinois Clinical Laboratories Code (77 Ill. Adm. Code 450) (see in particular Section 697.180(c) and (e));

4) ~~Blood Labeling Code (77 Ill. Adm. Code 460) (see in particular Section 697.180(e) and (e) of this Part);~~

D)5) Sperm Bank and Tissue Bank Code (77 Ill. Adm. Code 470) (see in particular Section 697.180(c) and (e));

E)6) ~~Rules of Practice and Procedure in Administrative Hearings (77 Ill. Adm. Code 100) (see in particular Section 697.40 of this Part);~~

7) ~~Illinois Blood Bank Code (77 Ill. Adm. Code 490);~~

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)

I) Illinois Veterans' Home Code (77 Ill. Adm. Code 340)

J) Intermediate Care for the Developmentally Disabled Facilities Code (77 Ill. Adm. Code 350)

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- K) Long-term Care for Under Age 22 Facilities Code (77 Ill. Adm. Code 390)
- 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 (Public Law 100-578, effective October 31, 1988)
 - B) Education for All Handicapped Children Act (Public Law 94-142, effective November 29, 1975)
- b) The following materials are incorporated by reference in this Part:
 - 1)e) Federal ~~Regulations~~Rules
 - 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)d) Other ~~Codes, Guidelines and Standards~~
 - A) Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health-Care Settings, Centers for Disease Control and Prevention, Morbidity and Mortality Weekly Report (MMWR), September 22, 2006, Vol. 55, No. RR-14
 - B) Recommendations for Use of Antiretroviral Drugs in Pregnant HIV-1-Infected Women for Maternal Health and Interventions to

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Reduce Perinatal HIV Transmission in the United States, May 24, 2010; US Department of Health and Human Services, Panel on Treatment of HIV-Infected Pregnant Women and Prevention of Perinatal Transmission (A Working Group of the Office of AIDS Research Advisory Committee)

- 1) ~~1993 Revised Classification System for HIV Infection and Expanded Surveillance Case Definition for AIDS Among Adolescents and Adults, Centers for Disease Control and Prevention (CDC). Morbidity and Mortality Weekly Report (MMWR), December 18, 1992; vol. 41, no. RR-17.~~
- 2) ~~1994 Revised Classification System for HIV Infection for Children Less Than 13 Years of Age. Centers for Disease Control and Prevention (CDC). Morbidity and Mortality Weekly Report (MMWR), vol. 43 (RR-12).~~
- 3) ~~The "Adult HIV/AIDS Confidential Case Report", as modified by the Department, a form prepared by the Centers for Disease Control and Prevention, Public Health Service, U.S. Department of Health and Human Services, Atlanta, Georgia 30333, Office of Management and Budget No. 0920-0009 (1993). (See Section 697.210.)~~
- 4) ~~Guidelines for the Management of Chronic Infectious Diseases in School Children. (See Section 697.410.)~~
- 5) ~~1993 Revised Classification Scheme for HIV Infection and Expanded Surveillance Case Definition for AIDS Among Adolescents and Adults, Centers for Disease Control and Prevention, Morbidity and Mortality Weekly Report (MMWR). Vol. 41, No. RR-17, December 18, 1992, Public Health Service, U.S. Department of Health and Human Services, Atlanta, Georgia 30333.~~
- 6) ~~Recommendations for Use of Antiretroviral Drugs in Pregnant HIV-1-Infected Women for Maternal Health and Interventions to Reduce Perinatal HIV-1 Transmission in the United States, Public Health Service Task Force, U.S. Department of Health and Human Services, Atlanta, Georgia 30333 (August 30, 2002).~~

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- 7) ~~Updated U.S. Public Health Services Guidelines for the Management of Occupational Exposures to HBV, HCV, and HIV and Recommendations for Postexposure Prophylaxis, Centers for Disease Control and Prevention (CDC), Morbidity and Mortality Weekly Report (MMWR), Vol. 50, No. RR-11, June 29, 2001, Atlanta, Georgia 30333.~~
- 8) ~~Revised Guidelines for HIV Counseling, Testing and Referral, Centers for Disease Control and Prevention (CDC), Morbidity and Mortality Weekly Report (MMWR), Vol. 50, No. RR-19, November 9, 2001, Atlanta, Georgia 30333.~~
- 9) ~~Revised Recommendations for HIV Screening of Pregnant Women, Centers for Disease Control and Prevention (CDC), Morbidity and Mortality Weekly Report (MMWR), Vol. 50, No. RR-19, November 9, 2001, Atlanta, Georgia 30333.~~
- 10) ~~Advancing HIV Prevention: New Strategies for a Changing Epidemic—United States 2003, Centers for Disease Control and Prevention (CDC), Morbidity and Mortality Weekly Report (MMWR), Vol. 52, No. 15, April 18, 2003, Atlanta, Georgia 30333.~~

- e) ~~All citations to federal regulations in this Part concern the specified regulations in the 1994 Code of Federal Regulations, unless another date is specified.~~
- c)f) All incorporations by reference of federal regulations or ~~guidelinesstandards and the standards of nationally recognized organizations~~ refer to the regulations or guidelinesand standards on the date specified and do not include any amendments or editionsadditions or deletions subsequent to the date specified.

(Source: Amended at 36 Ill. Reg. _____, effective _____)

Section 697.40 Administrative Hearings

Any administrative hearings conducted by the Department concerning ~~the provisions of~~ this Part shall be governed by the Department's ~~Rules of~~ Practice and Procedure in Administrative Hearings ~~(See 77 Ill. Adm. Code 100).~~

(Source: Amended at 36 Ill. Reg. _____, effective _____)

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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 ~~presenceevidence~~ of ~~infection with HIV~~ infection shall use an approved HIV test as defined in this Part~~tests approved by the FDA.~~ (See Section 697.20.)
- b) ~~Testing for the presence of antibodies to the HIV virus shall consist of the following:~~
- ~~1) For the conventional HIV test, every sample shall be tested with an approved screening test. If the test is found to be reactive (according to the package insert or product circular), a second screening test, in duplicate, shall be conducted as soon as possible. If the second screening test is also found to be reactive, then a supplemental test shall be conducted. If the supplemental test is found to be reactive (according to the package insert or product circular), then the sample shall be considered to indicate the presence of antibodies to HIV or to be positive.~~
 - ~~2) For the rapid HIV test, every sample shall be tested with an approved HIV rapid antibody screening test. If the test is found to be reactive (according to the package insert or product circular), it will be considered preliminary positive and a supplemental test shall be conducted. Before the supplemental test, a second sample shall be obtained, if necessary, to ensure an adequate sample amount. If the supplemental test is found to be reactive (according to the package insert or product circular), then the sample shall be considered to indicate the presence of antibodies to HIV or to be positive.~~
 - ~~3) For both the conventional and rapid HIV tests, if the supplemental test is found to be indeterminate, then the specimen should be tested with another supplemental test. If the sample is found to be reactive (according to the package insert or product circular), then the sample shall be considered to indicate the presence of antibodies to HIV or to be positive.~~
- 1)4) Confirmatory~~All phases of testing required by this Section~~ shall be completed before HIV test results are released to the health care

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~~professional physician~~ or other individuals authorized to receive the results as described and limited in Section 697.140, except in the following situations that, as allowed under subsection (b)(6), reactive results from rapid HIV antibody tests may be released to individuals authorized to receive the results under the following circumstances:

- A) ~~When~~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)(b)(4)~~, 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 ~~[410 ILCS 335]~~) 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 guidelines of the U.S. Public Health Service for reducing perinatal HIV transmission in the United States (see Section 697.30);
- B) ~~In~~in instances of occupational exposure, as provided by Section 697.140(a)(8) and (9); or
- C) ~~At~~at the time of testing, ~~or immediately thereafter,~~ 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. counseling that includes the limitations of the test and the need for supplemental testing, as well as appropriate risk reduction measures and referrals, and that the individual has consented to a rapid HIV antibody test and to the receipt of preliminary result.

- ~~2)5)~~ Before testing is conducted under subsection ~~(a)(1)(b)(4)~~(A) ~~or~~, (B) ~~or~~ (C), the subject of the test or the subject's legally authorized representative shall receive pre-test information~~have been counseled~~ 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

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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)6)~~ In ~~such cases as~~ the exceptions described in ~~subsections~~ (a)(1)(b)(4)(A) or (B) or (C), a preliminary test result may be released to persons specified in Section 697.140(a)(1), (2), (3), (8), or (9).
- ~~4)7)~~ Any release of preliminary positive results from ~~rapid~~ HIV ~~antibody~~ tests shall include a disclaimer that an HIV ~~infection~~ positive diagnosis has not been ~~diagnosed~~ made and cannot be ~~diagnosed~~ made without supplemental testing.
- ~~8)~~ ~~Any subject or subject's legally authorized representative receiving test results will receive counseling that includes the limitations of the test, appropriate risk reduction measures, appropriate referrals, and, if the test result is reactive, information on partner notification programs prior to being informed of the results.~~
- 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. _____, effective _____)

Section 697.110 HIV Pre-Test Information

- a) ~~No health care professional~~ physician may order an HIV test without making available to the person tested ~~pre-test~~ pre-test information, except as provided in subsection (b) ~~below~~. (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

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testing. (Section (3)(d) of the Act) The health care professional may delegate the responsibility of providing pre-test information ~~only may not be delegated by the physician. However, the task of providing pre-test information to the patient may be delegated~~ to another ~~individual health care provider~~ who is knowledgeable about HIV infection, including possible medical and psychosocial aspects of ~~the such~~ 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 About the meaning of the test results, including (such as the purpose, potential uses, and limitations of the test and test results, and procedures to be followed, and the statutory rights to anonymous testing and to confidentiality);~~
 - 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;
 - 2) ~~The availability of additional or confirmatory testing, if appropriate (See Section 697.100(b)), and~~
 - 3) ~~The availability of referrals for further information or counseling (Section 5 of the AIDS Confidentiality 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 ~~following~~ situations listed in Section 697.120 (b)(1), (2), (5) and (7).:
- 1) ~~When the Health Care provider or health facility procures processes, distributes or uses a human body part donated for purposes specified under the Uniform Anatomical Gift Act or the Organ Donation Request Act and the test is performed to assure the medical acceptability of the human body part. (Section 7 of the AIDS Confidentially Act.)~~

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- 2) ~~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 AIDS Confidentiality Act.)~~
- 3) ~~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, as amended, requires any insured patient or applicant for new or continued insurance or coverage to be tested for infection with HIV virus or any other identified causative agent of AIDS. (Section 3 of AN ACT concerning certain rights of medical patients, Ill. Rev. Stat. 1987, ch. 111½, par. 5403). (See Section 697.170.)~~
- 4) ~~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 AIDS Confidentiality Act).~~

(Source: Amended at 36 Ill. Reg. _____, effective _____)

Section 697.120 ~~Written~~ Informed Consent

- a) ~~No person may order an HIV test without first receiving the documented~~written~~, 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 ~~AIDS Confidentiality~~ Act)~~
- 1) ~~The~~~~This~~ written informed consent and test results must be obtained by the health care professional~~physician~~ ordering the test or ~~by another health care professional~~~~physician~~ involved in the patient's care shall obtain the informed consent.

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- 2) ~~The health care professional may delegate the~~The responsibility of obtaining ~~written~~ informed consent ~~only may not be delegated by the physician. However, the task of obtaining written informed consent from the patient may be delegated~~ to another ~~individual health care provider~~ who is knowledgeable about HIV infection, including possible medical and psychosocial aspects of ~~that such~~ 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~~~~Written informed~~ consent to perform an HIV test is not required in the following situations:
- 1) ~~When the health care professional~~~~provider~~ or health ~~care~~ facility procures, processes, distributes or uses a human body part donated for purposes specified under the ~~Illinois Uniform~~ Anatomical Gift Act or the Organ Donation Request Act and the test is ~~necessary~~~~performed~~ to assure the medical acceptability of the human body part. (Section 7 of the ~~AIDS Confidentiality~~ Act)
 - 2) ~~When the health care professional~~~~provider~~ or health ~~care~~ facility procures, processes, distributes or uses semen provided prior to September 21, 1987, for the purpose of artificial insemination and ~~the~~~~the~~ test is ~~necessary~~~~performed~~ to assure ~~the~~ medical acceptability of ~~the~~~~the~~ semen. (Section 7 of the ~~AIDS Confidentiality~~ Act)
 - 3) ~~When the testing is~~~~When the testing is~~ for the purpose of research ~~and~~~~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

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subject is not informed of the results of the testing. (Section 8 of the ~~AIDS Confidentiality~~ Act)

- 4) ~~When an HIV test is performed~~*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, ~~immigrants to the United States,~~ and persons required to be tested pursuant to Section 5-5-3 of the Unified Code of Corrections). (Section 11 of the ~~AIDS Confidentiality~~ 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* ~~fraternal benefit society, health services corporation, health maintenance organization, or any other insurer subject to regulation under the Illinois Insurance Code, as amended~~ 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 ~~[410 ILCS 50/3]~~) (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.* ~~When a health care provider or employee of a health facility, or a firefighter or an Emergency Medical Technician-Ambulance (EMT-A), Emergency Medical Technician-Intermediate (EMT-I) or Emergency Medical Technician-Paramedic (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 medical judgment. Should such test prove to be positive, the patient shall be provided appropriate counseling consistent with this Act.~~ (Section 7 of the ~~AIDS Confidentially~~ Act)-
- 7) *When in the judgment of the physician, such testing is medically indicated*

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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 ~~AIDS Confidentiality Act~~)-

- 8) *For a health care ~~professional provider~~ 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~~this Act. For purposes of Section 7(c) of the Act, "~~law enforcement officer~~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~~persons life. (Section 7 of the ~~AIDS Confidentiality 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. _____, effective _____)

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. Any person upon whom an HIV test is performed shall have the right to request anonymity and to provide written informed consent by using a coded system that does not link individual identity with the request or the result except when written informed consent is not required by law as specified in Section 697.120. (Section 6 of the ~~AIDS Confidentiality Act~~.) Any anonymous testing system adopted by the health care ~~professional provider~~ ordering the test ~~shall~~must ensure that the persons conducting the laboratory tests transmit the correct test results ~~are transmitted by the persons conducting the laboratory tests~~ to the proper health care professional physician, and that the correct test results

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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 in such a manner~~ as to prevent ~~any person~~ ~~persons~~ from learning the identity of the test subject, unless ~~the person~~ ~~is such persons are~~ authorized to receive ~~the such~~ information pursuant to Section 697.140 of this Part.

- a) If anonymous testing is requested, the ~~health care professional~~ ~~physician~~ shall assign to ~~the such~~ person a unique number or notation, which shall be used ~~by the person to sign the written informed consent~~ in lieu of the person's name. The ~~specimen~~ ~~blood sample~~ for testing shall be labeled with the ~~physician's~~ 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 ~~in order~~ to comply with ~~the provisions of~~ Section 697.140(a)(3) or (6) of this Part;⁵ or
 - 2) If the test is performed ~~in order~~ 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. _____, effective _____)

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 ~~AIDS Confidentiality 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.~~

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- 1) *The subject of the test or the subject's legally authorized representative* (Section 9(a) of the ~~AIDS Confidentiality 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 ~~AIDS Confidentiality Act~~) A legally effective release means a time-limited written release of medical information ~~specific to HIV test results~~ signed by the test subject. ~~A general release is not sufficient. A single form may be used to authorize the release of medical records including HIV information provided such form specifically authorizes the release of any HIV information. Any such release, under this subsection (a)(2), must not reveal whether or not HIV information exists.~~
- 3) *An authorized agent or employee of a health care facility or health care professional~~provider~~ or referring, treating or consulting health care professional~~physician, dentist, or podiatrist~~ of the test subject, if:*

 - A) *The health care facility or health care professional~~provider itself~~ is authorized to obtain the test results.* ~~(Health care facility or health care professional~~provider~~, for the purposes of this subsection (a)(3)(A), includes ~~the medical records or similar~~ personnel who handle and process medical records for that health care facility or health care professional~~provider~~.);~~
 - B) *The agent or employee or referring, treating or consulting health care professional~~physician, dentist, or podiatrist~~ of the test subject provides patient care or handles or processes specimens of body fluids or tissues;* ~~and~~
 - C) *The agent or employee or the test subject's referring, treating or consulting health care professional~~physician of the test subject~~ has a need to know such information.* (Section 9(c) of the ~~AIDS Confidentiality Act~~); ~~and An authorized agent or employee of a health facility or health care provider or referring, treating or consulting physician, dentist, or podiatrist has a need to know the identity of the patient or the test results revealing the identity of the patient under the following circumstances:~~

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- 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 ~~AIDS Confidentiality~~ Act)
 - 7) A school principal in accordance with ~~the provisions of~~ Section 697.400 of this Part.
 - 8) *Any health care ~~professional provider~~ or employee of a health care facility, and any firefighter or any EMT-~~BA~~, EMT-I, ~~EMT-PEMT-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 ~~AIDS Confidentiality~~ 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 ~~AIDS Confidentiality~~ 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, ~~as now or hereafter amended.~~* (Section 9(j) of the ~~AIDS Confidentiality~~ Act)
- b) HIV test results may be disclosed to ~~health care providers and~~ 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~~reactive results from rapid HIV antibody tests~~ in a manner that permits the identification of the subject of the test, except in accordance with Section 697.100~~(a)(1)(b)(4)~~.

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- d) ~~Documentation of informed consent, including written forms, if any, The written informed consent form~~ and HIV test results may be maintained, documented, and transmitted in a confidential manner in an electronic medical record system, medical record ~~and/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 ~~AIDS Confidentiality~~ Act)
 - 2) *Nothing in the Act or this Part shall be construed to impose civil or criminal sanction for performing a test without ~~written~~ informed consent pursuant to the provisions of ~~subsection (b) or (c) of~~ Section 7 ~~(b) or (c) of~~ the ~~AIDS Confidentiality~~ Act.* (Section 15 of the ~~AIDS Confidentiality~~ Act)
 - 3) ~~The~~ *The intentional or reckless violation of the ~~Act or this Part~~ ~~AIDS Confidentiality Act or any regulation issued under that Act~~ shall constitute a ~~Class A~~ ~~Class A~~ misdemeanor.* (Section 12 of the ~~AIDS Confidentiality~~ 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~~ ~~Illinois Insurance Code~~.* (Section 15.1 of the ~~AIDS Confidentiality~~ Act)

(Source: Amended at 36 Ill. Reg. _____, effective _____)

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*

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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 test 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;

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- 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. _____, effective _____)

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 ~~the provisions of~~ Sections 697.110, 697.120, 697.130 and 697.140 in establishing eligibility and coverage requirements ~~that which~~ include mandatory HIV tests. This exemption also extends to the physician or other health care ~~professional provider~~ that performs ~~thesuch~~ tests.
- b) Health maintenance organizations, insurance companies, fraternal benefit societies, health services corporations and other insurers subject to ~~regulation under~~ the Illinois Insurance Code ~~that require that require~~ any insured patient or applicant for new or continued insurance or coverage to be tested for HIV infection with Human Immunodeficiency Virus (HIV) or any other identified causative agent or Acquired Immunodeficiency Syndrome (AIDS) 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 2.02 of "AN ACT concerning certain rights of medical patients")*

(Source: Amended at 36 Ill. Reg. _____, effective _____)

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Section 697.170 Enforcement of the AIDS Confidentiality Act

- a) All health care facilities and health care professionals~~providers~~ are required to comply with ~~the provisions of~~ this Part. Any failure to comply will be addressed in accordance with the following:
- 1) Health care facilities and health care professionals~~providers~~ 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, as such provisions~~ are applicable to the health care facilities and health care professionals~~providers~~ as a condition of ~~such~~ licensure, certification, permit or any other form of recognition by the Department. The reckless, deliberate or conscious failure to comply with ~~these~~such 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~~state, federal, or local regulatory agency, any complaint ~~that~~which it receives concerning the failure by any health care facility or health care professional ~~that~~provider, which is subject to regulation by ~~that~~such agency, to comply with the applicable provisions of Sections 697.110, 697.120, 697.130 and 697.140 ~~of this Part, as such provisions are applicable to the health facilities and health care providers.~~
- b) ~~The~~The intentional or reckless violation of the Act~~the AIDS Confidentiality Act or this Part~~any regulations issued thereunder shall constitute a Class A~~class B~~ misdemeanor. (Section 12 of the ~~AIDS Confidentiality 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.~~Civil remedy provisions can be found in Section 13 of the AIDS Confidentiality Act.~~
- 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.

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- 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. _____, effective _____)

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 ~~in order~~ to determine whether ~~or not~~ 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 ~~written~~ informed consent provisions of Section 697.120 of this Part are ~~not~~ required.
- b) If ~~permission for~~ HIV testing is ~~refused not given~~, ~~then~~ the person shall not be accepted as a donor.
- c) The results of HIV testing shall be ~~delivered~~~~disclosed~~ in accordance with ~~the provisions of~~ Section 697. ~~155 and 140 of this Part~~, 77 Ill. Adm. Code 450, ~~77 Ill. Adm. Code 460~~, ~~77 Ill. Adm. Code 490~~ and ~~77 Ill. Adm. Code~~ 470.
- d) The results of HIV testing shall be kept confidential in accordance with ~~the provisions of~~ Section 697.140 ~~of this Part~~.
- e) The donated blood, plasma, semen, oocytes, organs or other human tissue shall be handled in accordance with ~~the provisions of~~ 77 Ill. Adm. Code 450, ~~77 Ill. Adm. Code 460~~, ~~77 Ill. Adm. Code 490~~ and ~~77 Ill. Adm. Code~~ 470.

(Source: Amended at 36 Ill. Reg. _____, effective _____)

SUBPART C: HIV/AIDS REGISTRY SYSTEM

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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/AIDS treatment and prevention measures. The HIV/AIDS Registry System is a compilation of information concerning reported~~diagnosed~~ cases of AIDS and HIV.

(Source: Amended at 36 Ill. Reg. _____, effective _____)

Section 697.210 Reporting Requirements

- a) Local health authorities that~~Health Authorities which~~ receive HIV/AIDS reports from health care professionals~~physicians~~, hospitals or laboratories shall report to the Department's HIV/AIDS Registry System within seven days after receiving the HIV/AIDS report. ~~Prior to forwarding an HIV report to the Department, a Local Health Authority shall replace an individual's name with a unique identifier derived by methodology specified by the Department. (See Control of Sexually Transmissible Disease Code, 77 Ill. Adm. Code 693.30.)~~
- b) ~~The report shall be provided upon the "HIV/AIDS Confidential Case Report", as modified by the Department, a form prepared by the Centers for Disease Control and Prevention, Public Health Service, U.S. Department of Health and Human Services, Atlanta, Georgia 30333, OMB No. 0920-0009 and supplied by the Department.~~
- b) The Department requests, but does not require, hospitals, clinics, military facilities and prisons maintained by the federal government~~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. _____, effective _____)

Section 697.220 Release of HIV/AIDS Registry Data~~Information~~

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

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- 1) *It is in a statistical form that does not identify the reporting entity, physician ~~and/or~~ 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~~information concerning a person who is residing in that jurisdiction. The Department shall disclose individual patient ~~data~~information 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 ~~the 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~~such a request in the opinion of the test subject's health care professional~~physician~~. (Section 7(c) of the HIV/AIDS Registry Act)*
- 1) *All requests by medical or epidemiologic researchers for confidential HIV/AIDS Registry data ~~shall~~must be submitted in writing to the ~~Department~~Registry. The request ~~shall~~must include a study protocol ~~that~~which 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~~physicians~~ or study*

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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~~~~insure~~ 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~~~~must~~ 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~~~~which~~ 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~~~~which require~~ 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 ~~only~~ release only the patient or facility identifying information ~~that~~~~which~~ is

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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 ~~and all~~ data ~~that which~~ may lead to the identity of any patient, research subject, health care professional, physician, other person, or hospital ~~is are~~ strictly privileged and confidential and agrees to keep all ~~such~~ data strictly confidential at all times;
 - C) The researcher understands that all officers, agents and employees are to keep all ~~such~~ 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 ~~only~~ 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.

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- 4) Any departures from the approved protocol ~~shall~~**must** be submitted in writing and approved by the Director in accordance with subsection (c)(2) ~~of this Section~~ 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~~**which** originally supplied that information to the Department, upon written request of the facility.
- d) HIV/AIDS information may be disclosed in accordance with ~~the provisions of~~ Sections 697.140 and 697.400 ~~of this Part~~.
- e) *No liability shall attach to any hospital, physician or other facility submitting information pursuant to ~~the~~**this** 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. _____, effective _____)

SUBPART D: HIV COUNSELING AND TESTING CENTERS

Section 697.300 HIV Counseling and Testing Centers (Repealed)

- a) ~~The Department shall establish alternative blood and HIV test services, known as HIV Counseling and Testing Centers. (Section 2310-315 of the Civil Administrative Code of Illinois) These facilities shall be operated by the Department or Designated Agencies. These facilities shall provide services in accordance with the provisions of this Part and the applicable provisions of the Sexually Transmissible Diseases Code (77 Ill. Adm. Code 693, specifically Sections 693.40, 693.70, 693.80, 693.90, 693.100, 693.120, 693.130 and 693.140.)~~
- 1) ~~These facilities shall not be operated by blood banks, plasma centers or hospitals. (Section 2310-315 of the Civil Administrative Code of Illinois)~~
- 2) ~~Physicians and other health care providers may refer HIV-infected persons to these facilities for counseling.~~

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- ~~3) Any person twelve years of age or older may consent to testing and counseling at an HIV Counseling and Testing Center.~~
- b) ~~No person may be subjected to an HIV antibody test at HIV Counseling and Testing Centers, unless written informed consent is first obtained from the test subject or the test subject's legally authorized representative. (See Appendix A, Illustration A for a Sample Written Informed Consent Form.)~~
- e) ~~All persons seeking counseling and testing at an HIV Counseling and Testing Center shall be offered the option of confidential or anonymous services and shall provide written informed consent using a coded system. All patient records shall be maintained using this code system.~~
- d) ~~The HIV Counseling and Testing Centers shall provide counseling to the test subject prior to performing the test. The counseling shall include, but not necessarily be limited to, information about:~~
- ~~1) HIV infection and HIV transmission;~~
 - ~~2) the difference between confidential and anonymous HIV testing; information about the meaning of the test and test results; such as the purpose, potential uses, and limitations of the test and test results and the statutory rights to anonymous testing and to confidentiality; and information about the availability of supplemental testing;~~
 - ~~3) the availability of referrals for further information, or counseling; and~~
 - ~~4) methods for prevention of transmission of HIV.~~
- e) ~~Contact interview and investigation services shall be provided only by counselors who have completed a course of training that included instruction in the following:~~
- ~~1) The etiology and transmission of HIV, including associated risk behaviors and activities and patient profiles of persons at significant risk of HIV infection;~~
 - ~~2) The natural history and progression of HIV infection;~~

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- ~~3) Methods for preventing transmission of HIV infection;~~
 - ~~4) Principles and techniques of counseling, including demonstration of interviewing and counseling skills needed for epidemiologic management of HIV-infected persons, critiqued role playing, psychological assessment and crisis intervention;~~
 - ~~5) Principles and techniques of contact investigation and referral; and~~
 - ~~6) Principles of communicable diseases.~~
- ~~f) It shall be the duty of every person providing results of an HIV antibody test to provide the subject of the test with an explanation of the test results, methods for prevention of HIV transmission, and referrals for medical and psychological follow-up appropriate to the needs of the test subject. These referrals shall include appropriate referrals to physicians who will provide services to HIV positive individuals; tuberculosis and sexually transmissible disease services facilities for psychological counseling; and crisis intervention and substance abuse treatment facilities, as available.~~
- ~~g) All persons with a positive HIV antibody test shall be offered the assistance of health professionals in locating and referring sexual and needle-sharing contacts for counseling and testing, with the consent of the infected person. All persons refusing such assistance shall be strongly encouraged to notify their previous sexual and needle-sharing contacts of their possible exposure to HIV, and to refer such contacts for counseling and possible testing.~~
- ~~1) HIV-infected persons shall be asked to identify their sexual and needle-sharing contacts for the preceding 12-month period. The counselor shall discuss the specific nature of each contact with the client to determine the likelihood of HIV transmission based on the type of sexual or needle-sharing practice involved and the counselor's knowledge of risk factors.~~
 - ~~2) Those contacts determined to be at significant risk of infection, in the professional judgment of the counselor based on the type of sexual or needle-sharing practice involved and the counselor's knowledge of risk factors, shall be investigated. Investigation shall be conducted for contacts for whom sufficient information to identify the person is available, such as first and last name, street address, or telephone number.~~

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- 3) ~~The counselor may prioritize the order in which contacts are to be investigated. The counselor shall provide first priority to those contacts who (based again on the counselor's professional judgment), except for contact notification, may not have reason to suspect they may be infected because the counselor has no information that the contacts:~~
 - A) ~~are aware of having engaged in behavior likely to result in exposure; and/or~~
 - B) ~~are knowledgeable about the type of behavior carrying such risks.~~
- 4) ~~Persons choosing to self-refer their contacts shall receive intensive individualized instruction and counseling in methods to provide this notification and referral.~~
- 5) ~~Contacts to persons with HIV infection, identified through the contact interview and investigative process, shall be counseled, confidentially and in person, regarding the possibility of infection, methods to prevent the spread of the infection, and services available from public health agencies. Such persons shall also be offered testing to determine infection.~~
- 6) ~~If such person is legally unable to agree to counseling because of age or legal incompetence, consent and participation in counseling shall be requested of the individual's parent or legal guardian. If such person is legally able to agree to but appears to be incapable of understanding and competently acting on such counseling, in the professional judgment of the counselor, participation in counseling shall be requested of a parent or other person chosen by the client.~~
- h) ~~It shall be the duty of every person conducting an HIV test in an HIV Counseling and Testing Center to provide results of the test only to the individual upon whom the test was performed. Such results are to be provided only in an individual face-to-face interview. The test subject may elect to have other persons present during the interview. It shall be the duty of the person providing the counseling to determine that the presence of a second party during the interview is not the result of undue inducement such as any element of force, fraud, deceit or other constraint or coercion.~~

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- i) ~~It shall be the duty of every person with access to an individual's HIV antibody test results to maintain strict confidentiality of those results and the test subject's identity as required by the Act and as specified in Section 697.140.~~

(Source: Repealed at 36 Ill. Reg. _____, effective _____)

SUBPART E: MISCELLANEOUS PROVISIONS

Section 697.400 Notification of School Principals

- a) ~~Whenever a child of school age is reported to the Department or to a local health department with a confirmed HIV infection, the Department or local health authority as having been diagnosed as having AIDS or as having been shown to have been exposed to Human Immune Deficiency Virus (HIV) (or any other identified causative agent of AIDS) by testing positive on a Western Blot Assay or more reliable tests as specified in Section 697.100, such department 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 [410 ILCS 315/2a]). School age is defined as between ages 5 and 21 by Section 10-20.12 of the School Code [105 ILCS 5/10-20.12] and between ages 3 and 21 for handicapped children by the Education for All Handicapped Children Act (20 U.S.C. Section 1412(1)(B)). Diagnosed cases and laboratory results are reported to the Department in accordance with the provisions of the "Control of Sexually Transmissible Infections Diseases Code" (77 Ill. Adm. Code 693). If the child resides in a county or city governed by a full-time Local Health authority, such notification shall be the responsibility of the Local Health authority. In all other cases, such 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, upon receipt of such 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 such services, disclose the identity of an infected child to the school nurse at that school, the classroom teachers in whose classes the child is~~

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enrolled, and those persons who, pursuant to ~~federal~~Federal or ~~State~~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 ~~[410 ILCS 315/2a]~~)

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

(Source: Amended at 36 Ill. Reg. _____, effective _____)

Section 697.410 Guidelines for the Management of Chronic Infectious Diseases in School Children ~~(Repealed)~~

~~The management of the child in the classroom should be in accordance with the following guidelines developed jointly by the Department and the State Board of Education, "Guidelines for Management of Chronic Infectious Diseases in School Children."~~

(Source: Repealed at 36 Ill. Reg. _____, effective _____)

Section 697.420 Testing, Treatment or Counseling of Minors

~~Any person 12Any person ~~twelve~~ years of age or older who may have come in contact with any ~~STI~~STD, such as AIDS or HIV infection may consent to testing and to medical care and/or counseling related to the diagnosis and/or treatment of such ~~STI~~diseases. (Section 4 of the Consent by Minors to Medical Procedure Act ~~[405 ILCS 210/4]~~)~~

(Source: Amended at 36 Ill. Reg. _____, effective _____)

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Section 697.APPENDIX A Sample HIV Testing Forms **(Repealed)**

Section 697.ILLUSTRATION A Sample Written Informed Consent for HIV Antibody Testing **(Repealed)**

**~~WRITTEN INFORMED CONSENT FOR HIV ANTIBODY TESTING
(Conventional Testing – Not for Use with a Rapid HIV Test)~~**

Test Subject or Number: _____ Date: _____
Time: _____ (AM)(PM)

~~I hereby grant my permission for a test to detect whether I have antibodies to HIV (Human Immunodeficiency Virus) in my body.~~

~~HIV Testing is voluntary and requires your consent in writing. The purpose of HIV antibody testing is to show whether you are infected with HIV, the virus that causes AIDS.~~

~~Any test result that indicates that antibodies for HIV are present is considered positive for HIV infection.~~

~~Before you consent to be tested for HIV, your healthcare provider should speak to you about:~~

- ~~▪How HIV is passed from person to person and mother to baby;~~
- ~~▪Steps to take that may prevent the transmission of HIV; and~~
- ~~▪The meaning of an HIV antibody test result.~~

~~If you agree with the following statements and want to consent to HIV testing, please sign this form.~~

~~I have been counseled about the benefits of having an HIV test and understand that:~~

- ~~▪Human immunodeficiency virus (HIV) is the virus that causes AIDS;~~
- ~~▪HIV is spread by sexual intercourse, so all sexually active persons are potentially at risk for HIV infection;~~
- ~~▪HIV is spread by sharing needles with another person during injection of drugs, so all injection drug users are potentially at risk for HIV infection;~~
- ~~▪HIV can be passed from a mother to her baby during pregnancy, at delivery, and through~~

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~~breastfeeding; and~~

~~▪ HIV antibody test results are confidential, and the law protects me from discrimination.~~

~~I understand that a positive result does not mean I have AIDS, but indicates that I have HIV infection. I understand that if my test results are positive, I will be offered HIV counseling.~~

~~I understand that test results may indicate that a person has HIV antibodies when the person does not have the antibodies (a false positive result) or the test may fail to detect that a person has antibodies to the virus when the person does in fact have these antibodies (a false negative result).~~

~~If my HIV antibody test result is negative, no further testing will be done at this time. A negative HIV antibody test result most likely means that I am not infected with HIV, but it may not detect recent infection.~~

~~If my HIV antibody test result is positive, this means that antibodies to the virus were detected and that I am HIV infected.~~

~~Confidentiality of HIV Information:~~

~~If you take the HIV test, your test results are confidential. Under Illinois law, confidential HIV information can be given only to people to whom you allow it to be given by your written approval, to people who need to know your HIV status in order to provide medical care and services, including: an authorized agent or employee of a health facility or a healthcare provider if the health facility or provider is authorized to obtain test results; those who are exposed to blood/body fluids in the course of their employment; and organizations that review the services you receive.~~

~~The law also allows your confirmed HIV test results to be released: to public health officials as required by law; for payment for care and treatment; to a temporary caretaker of children taken into protective custody by the Illinois Department of Children and Family Services; and to any other entity permitted by the AIDS Confidentiality Act.~~

~~I understand that my test results will be kept confidential to the extent provided by law. In addition, I understand that I may withdraw from the testing at any point in time prior to the completion of laboratory tests. I understand that my testing is voluntary.~~

~~I agree to be tested and I agree that I may be told my test results.~~

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~~I agree that if the result of my HIV test is positive I may be referred to another healthcare provider for follow-up testing and care.~~

~~I have been advised about the purpose, potential uses, limitations and meaning of the test results; the voluntary nature of the test; the right to withdraw consent at any time prior to the completion of laboratory tests; and the confidentiality protections under the law. The information presented above has been completely and clearly explained to me, and all of my questions have been answered. I hereby authorize my physician or facility to collect an oral or blood specimen and perform an HIV antibody test on that specimen.~~

~~Patient/Client Signature or Signature of Legally Authorized Representative~~

~~Date~~

~~Facility/Provider Witness~~

~~Date~~

(Source: Repealed at 36 Ill. Reg. _____, effective _____)

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Section 697. Appendix C Sample Written Informed Consent for Rapid HIV Antibody Testing (Repealed)

~~WRITTEN INFORMED CONSENT FOR RAPID HIV ANTIBODY TEST~~

Test Subject or Number: _____ Date: _____
Time: _____ (AM)(PM)

~~I hereby grant my permission for a rapid HIV test to detect whether I have antibodies to HIV (Human Immunodeficiency Virus) in my body.~~

~~HIV Testing is voluntary and requires your consent in writing. The purpose of rapid HIV testing is to show whether you are infected with HIV, the virus that causes AIDS.~~

~~Rapid HIV testing will allow you to receive a preliminary test result in less than 60 minutes. Any test result that indicates that antibodies for HIV are present is considered preliminary positive and must be confirmed.~~

~~Before you consent to be tested for HIV, your healthcare provider should speak to you about:~~

- ~~▪ How HIV is passed from person to person and mother to baby;~~
- ~~▪ Steps to take that may prevent the transmission of HIV; and~~
- ~~▪ The meaning of a preliminary positive HIV rapid test result and how a preliminary HIV rapid test result is confirmed.~~

~~If you agree with the following statements and want to consent to rapid HIV testing, please sign this form:~~

~~I have been counseled about the benefits of having a rapid HIV test and understand that:~~

- ~~▪ Human immunodeficiency virus (HIV) is the virus that causes AIDS;~~
- ~~▪ HIV is spread by sexual intercourse, so all sexually active persons are potentially at risk for HIV infection;~~
- ~~▪ HIV is spread by sharing needles with another person during injection of drugs, so all injection drug users are potentially at risk for HIV infection;~~
- ~~▪ HIV can be passed from a mother to her baby during pregnancy, at delivery, and through breastfeeding; and~~

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~~▪ HIV antibody test results are confidential, and the law protects me from discrimination.~~

~~I understand that a preliminary positive result does not mean I have AIDS, but indicates that I may have HIV infection.~~

~~I understand that preliminary positive test results may indicate that a person has HIV antibodies when the person does not have the antibodies (a false positive result) or the test may fail to detect that a person has antibodies to the virus when the person does in fact have these antibodies (a false negative result).~~

~~The rapid HIV test that I am consenting to take will provide me and my health care provider with preliminary HIV test results:~~

- ~~▪ If my rapid HIV test result is negative, no further testing will be done at this time.~~
- ~~▪ If my rapid HIV test result is negative, it most likely means that I am not infected with HIV, but it may not detect recent infection.~~
- ~~▪ If my rapid HIV test result is preliminary positive, this means there is a possibility that I am HIV infected. A second test, to confirm a preliminary positive HIV test result, will be done.~~
- ~~▪ I understand that if my rapid HIV test result is preliminary positive, I still may not have HIV infection, since a false positive test result can occur. A second test, to confirm a preliminary positive HIV test result, will be done.~~
- ~~▪ I understand that if my rapid HIV test result is preliminary positive, I will be offered HIV counseling.~~

Confidentiality of HIV Information:

~~If you take the rapid HIV test, your test results are confidential. Under Illinois law, confidential HIV information can be given only to people to whom you allow it to be given by your written approval, to people who need to know your HIV status in order to provide medical care and services, including: an authorized agent or employee of a health facility or a healthcare provider if the health facility or provider is authorized to obtain test results; those who are exposed to blood/body fluids in the course of their employment; and organizations that review the services you receive.~~

~~The law also allows your confirmed HIV test results to be released: to public health officials as required by law; for payment for care and treatment; to a temporary caretaker of children taken into protective custody by the Illinois Department of Children and Family Services; and to any other entity permitted by the AIDS Confidentiality Act.~~

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~~I understand that my rapid HIV test results will be kept confidential to the extent provided by law. In addition, I understand that I may withdraw from the testing at any point in time prior to the completion of laboratory tests. I understand that my testing is voluntary.~~

~~I agree to be tested using a rapid HIV test and I agree that I may be told my test results.~~

~~I have been counseled that if the result of the rapid HIV test is preliminary positive, then I must undergo additional testing to confirm whether I am HIV positive. I consent to that additional testing.~~

~~I agree that if the result of my rapid HIV test is preliminary positive or if the result of my rapid HIV test is confirmed positive, I may be referred to another health care provider for follow-up testing and care.~~

~~I have been advised about the purpose, potential uses, limitations and meaning of the test results; the voluntary nature of the test; the right to withdraw consent at any time, prior to the completion of laboratory tests; and the confidentiality protections under the law. The information presented above has been completely and clearly explained to me, and all of my questions have been answered. I hereby authorize my physician or facility to collect an oral or blood specimen and perform a rapid HIV test on that specimen.~~

~~Patient/Client Signature or Signature of Legally Authorized Representative~~

~~Date~~

~~Facility/Provider Witness~~

~~Date~~

(Source: Repealed at 36 Ill. Reg. _____, effective _____)