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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>
697.30	Amend
697.100	Amend
697.140	Amend
697.400	Repeal
- 4) Statutory 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].
- 5) A Complete Description of the Subjects and Issues Involved: This rulemaking implements Public Act 98-0353, which was passed on August 16, 2013 and removed the requirement to notify school principals of students enrolled in a school program who are HIV infected. Section 697.100 is being amended to change the word "confirmatory" to "supplemental," which is more in line with the new HIV testing algorithm, and to reference the definition of a supplemental test, which is included in Section 697.20.

The economic effect on 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: None
- 7) Will this rulemaking replace any emergency rulemaking currently in effect? No
- 8) Does this rulemaking contain an automatic repeal date? No
- 9) Does this rulemaking contain incorporations by reference? No

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- 10) Are there any other proposed rulemakings pending on this Part? No
- 11) Statement of Statewide Policy Objectives: This rule change will not affect any unit of local government that would require expenditures of local funds.
- 12) Time, Place and Manner in which interested persons may comment on this proposed rulemaking:

Interested persons may present their comments concerning this rulemaking within 45 days after the publication of this issue of the *Illinois Register* to:

Susan Meister  
Division of Legal Services  
Illinois Department of Public Health  
535 W. Jefferson St., 5<sup>th</sup> floor  
Springfield, Illinois 62761

217/782-2043  
[dph.rules@illinois.gov](mailto:dph.rules@illinois.gov)

- 13) Initial Regulatory Flexibility Analysis:
- A) Types of small businesses, small municipalities and not for profit corporations affected: School districts
- B) Reporting, bookkeeping or other procedures required for compliance: None
- C) Types of professional skills necessary for compliance: None
- 14) Regulatory Agenda on which this rulemaking was summarized: This rulemaking was not included on either of the two most recent Regulatory Agendas because the need for the rulemaking was not apparent when the Regulatory Agendas were prepared.”

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	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 Test 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

SUBPART D: HIV COUNSELING AND TESTING CENTERS

Section	
697.300	HIV Counseling and Testing Centers (Repealed)

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SUBPART E: MISCELLANEOUS PROVISIONS

Section

- 697.400 Notification of School Principals (Repealed)  
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. 7613, effective May 4, 2012; amended at 38 Ill. Reg. \_\_\_\_\_, effective \_\_\_\_\_.

SUBPART A: GENERAL PROVISIONS

**Section 697.30 Incorporated and Referenced Materials**

- a) The following materials are referenced in this Part:
- 1) Illinois Statutes

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- A) AIDS Confidentiality Act [410 ILCS 305]
- B) AIDS Registry Act [410 ILCS 310]
- ~~C) Communicable Disease Prevention Act [410 ILCS 315]~~
- ~~CD) Unified Code of Corrections [730 ILCS 5]~~
- ~~DE) Medical Patient Rights Act [410 ILCS 50]~~
- ~~EF) Perinatal HIV Prevention Act [410 ILCS 335]~~
- ~~EG) Civil Administrative Code of Illinois [20 ILCS 2310/55 to 55.45].~~
- ~~H) School Code [105 ILCS 5]~~
- ~~GI) Abused and Neglected Child Reporting Act [325 ILCS 5]~~
- ~~HJ) Illinois Insurance Code [215 ILCS 5]~~
- ~~IK) Consent by Minors to Medical Procedures Act [410 ILCS 210]~~
- ~~JL) Illinois Sexually Transmissible Disease Control Act [410 ILCS 325]~~
- ~~KM) Medical Practice Act of 1987 [225 ILCS 60]~~
- ~~LN) Perinatal HIV Prevention Act [410 ILCS 335]~~
- ~~MO) Criminal Code of 1961 [720 ILCS 5]~~
- ~~NP) Code of Civil Procedure [735 ILCS 5]~~
- ~~OQ) Illinois Anatomical Gift Act [755 ILCS 50]~~
- ~~PR) Organ Donation Request Act [755 ILCS 60]~~
- ~~S) Communicable Disease Prevention Act [410 ILCS 315]~~

2) Illinois Rules

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- A) Control of Communicable Disease Code (77 Ill. Adm. Code 690) (see in particular Section 697.140(a)(4) of this Part)
  - B) Control of Sexually Transmissible ~~Diseases~~ Infections Code (77 Ill. Adm. Code 693) (see in particular Sections 697.140(a)(4) and 697.210(a) of this Part)
  - C) Illinois Clinical Laboratories Code (77 Ill. Adm. Code 450) (see in particular Section 697.180(c) and (e))
  - D) Sperm Bank and Tissue Bank Code (77 Ill. Adm. Code 470) (see in particular Section 697.180(c) and (e))
  - E) Practice and Procedure in Administrative Hearings (77 Ill. Adm. Code 100) (see in particular Section 697.40 of this Part)
  - F) Hospital Licensing Requirements (77 Ill. Adm. Code 250)
  - G) Skilled Nursing and Intermediate Care Facilities Code (77 Ill. Adm. Code 300)
  - H) Sheltered Care Facilities Code (77 Ill. Adm. Code 330)
  - I) Illinois Veterans' Home Code (77 Ill. Adm. Code 340)
  - J) Intermediate Care for the Developmentally Disabled Facilities Code (77 Ill. Adm. Code 350)
  - 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 (42 USC 263(a))

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

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

1)     Federal Regulations

- A)     42 CFR 2a.4(a)-(j), 2a.6(a)-(b), and 2a.7(a)-(b), Protection of Identity – Research Subjects (~~April 4, 1979~~ October 1, 2004)
- 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~~ October 1, 2013)

2)     Other Guidelines

- 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 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)

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

(Source: Amended at 38 Ill. Reg. \_\_\_\_\_, effective \_\_\_\_\_)

SUBPART B: HIV TESTING

**Section 697.100 Approved HIV Tests and Testing Procedures**

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- a) Any person, laboratory, blood bank, hospital or other entity that conducts laboratory tests to detect the presence of HIV infection shall use an approved HIV test as defined in this Part. (See Section 697.20.)
  - 1) Supplemental ~~Confirmatory~~ testing shall be completed before HIV test results are released to the health care professional or other individuals authorized to receive the results as described and limited in Section 697.140, except in the following situations:
    - A) When immediate medical treatment is necessary to prevent further transmission of HIV to a newborn infant in labor, delivery and postpartum settings. For the purposes of this subsection (a)(1), immediate medical treatment, for a newborn infant, means *upon delivery or within 48 hours after the infant's birth*. (Section 10 of the Perinatal HIV Prevention Act) Treatment shall be conducted as provided by the Recommendations for Use of Antiretroviral Drugs in Pregnant HIV-1-Infected Women for Maternal Health and Interventions to Reduce Perinatal HIV Transmission in the United States (see Section 697.30);
    - B) In instances of occupational exposure, as provided by Section 697.140(a)(8) and (9); or
    - C) At the time of testing, provided that the subject of the test or the subject's legally authorized representative has received pre-test information, has been informed of his/her right to refuse testing, and has provided consent to be tested and to receive a preliminary test result in accordance with Sections 697.110 and 697.120, except in the case of a newborn infant as provided in the Perinatal HIV Prevention Act.
  - 2) Before testing is conducted under subsection (a)(1)(A) or (B) (C), the subject of the test or the subject's legally authorized representative shall receive pre-test information and shall have provided specific written or verbal informed consent to be tested and to receive a preliminary test result in accordance with Sections 697.110 and 697.120, except in the case of a newborn infant as provided in the Perinatal HIV Prevention Act. The provision of pre-test information and informed consent shall be documented in the patient's medical record or as part of the consent form for medical care or HIV testing completed by the patient.



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- 3) In the exceptions described in subsection (a)(1)(A) or (B) , a preliminary test result may be released to persons specified in Section 697.140(a)(1), (2), (3), (8), or (9).
- 4) Any release of preliminary positive results from HIV tests shall include a disclaimer that an HIV infection has not been diagnosed and cannot be diagnosed without supplemental testing.
- b) HIV testing shall be a routine part of general medical care, as recommended by the United States Centers for Disease Control and Prevention, Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health-Care Settings.
- c) The Department will conduct training, technical assistance, and outreach activities, as needed, to encourage routine opt-out HIV testing in health care settings.

(Source: Amended at 38 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 Act) The term "disclose" as used in this subsection (a) shall not prohibit internal use by a person, or a person's agents or employees, for the purposes of treatment, payment and health care operations, as those terms are defined in 45 CFR 164.501. Any internal use shall be limited to those agents or employees, and the minimum necessary information, needed to accomplish the intended purposes of treatment, payment or health care operations.
  - 1) *The subject of the test or the subject's legally authorized representative* (Section 9(a) of the Act).
  - 2) *Any person designated in a legally effective release of the test results executed by the subject of the test or the subject's legally authorized representative.* (Section 9(b) of the Act) A legally effective release means a time-limited written release of medical information signed by the test subject.

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- 3) *An authorized agent or employee of a health care facility or health care professional or referring, treating or consulting health care professional of the test subject, if:*
  - A) *The health care facility or health care professional is authorized to obtain the test results. Health care facility or health care professional, for the purposes of this subsection (a)(3)(A), includes personnel who handle and process medical records for that health care facility or health care professional;*
  - B) *The agent or employee or referring, treating or consulting health care professional of the test subject provides patient care or handles or processes specimens of body fluids or tissues;*
  - C) *The agent or employee or the test subject's referring, treating or consulting health care professional has a need to know such information. (Section 9(c) of the Act); or*
  - D) *The agent or employee when involved in an accidental direct skin or mucous membrane contact with the blood or bodily fluids of a patient that is of a nature likely to transmit HIV, such as needle stick or percutaneous exposure, as certified by a health care professional.*
- 4) *The Department or the local health authority, in accordance with rules for reporting and controlling the spread of disease, or as otherwise provided by State law. (See 77 Ill. Adm. Code 690, 693, 250, 300, 330, 340, 350, 370, 390, and 840.) The Department, local health department or designated agent shall not disclose information and records held by them relating to known or suspected cases of AIDS or HIV infection, publicly or in any action of any kind in any court or before any tribunal, board or agency. AIDS and HIV Infection shall be protected from disclosure in accordance with the provisions of Sections 8-2101 through 8-2105 of the Code of Civil Procedure. (Section 9(d) of the Act)*
- 5) *A health care facility or health care professional which procures, processes, distributes or uses:*
  - A) *A human body part from a deceased person with respect to medical information regarding the person; or*

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- B) *Semen provided prior to September 21, 1987, for the purpose of artificial insemination. (Section 9(e) of the Act)*
- 6) *Health care facility staff committees for the purpose of conducting program monitoring, program evaluation or service reviews conducted by, but not limited to, the Department, local health authority or designated agent. (Section 9(f) of the Act)*
- 7) ~~A school principal in accordance with Section 697.400 of this Part.~~
- 78) *Any health care professional or employee of a health care facility, and any firefighter or any EMT-B, EMT-I, EMT-P involved in an accidental direct skin or mucous membrane contact with the blood or bodily fluids of an individual which is of a nature that may transmit HIV, as determined by a physician in his or her medical judgment. (Section 9(h) of the Act)*
- 89) *Any law enforcement officer, as defined in subsection (c) of Section 7 of the Act, involved in the line of duty in a direct skin or mucous membrane contact with the blood or bodily fluids of an individual which is of a nature that may transmit HIV, as determined by a physician in his or her medical judgment. (Section 9(i) of the Act)*
- 910) *A temporary caretaker of a child taken into temporary protective custody by the Department of Children and Family Services pursuant to Section 5 of the Abused and Neglected Child Reporting Act. (Section 9(j) of the Act)*
- b) HIV test results may be disclosed to researchers when done in a manner that does not reveal the identity of the subject of the test. The de-identification of test results may be performed by an authorized agent or employee of a health facility or health care professional. Any test results that cannot be revealed without identifying the subject of the test shall be disclosed only in accordance with subsection (a). The Department shall disclose test results and demographic data without identifying information to researchers, in accordance with Section 697.220.
- c) No person may disclose unconfirmed HIV test results in a manner that permits the identification of the subject of the test, except in accordance with Section 697.100(a)(1).

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- d) Documentation of informed consent, including written forms, if any, and HIV test results may be maintained, documented, and transmitted in a confidential manner in an electronic medical record system, medical record or confidential fax that allows disclosure only to persons authorized to receive the information under subsection (a).
- e) Liability and Sanctions
  - 1) *Nothing in the Act or this Part shall be construed to impose civil liability or criminal sanction for disclosure of a test result in accordance with any reporting requirement of the Department for a diagnosed case of HIV infection, AIDS or a related condition. (Section 15 of the Act)*
  - 2) *Nothing in the Act or this Part shall be construed to impose civil or criminal sanction for performing a test without informed consent pursuant to the provisions of Section 7(b) or (c) of the Act. (Section 15 of the Act)*
  - 3) *The intentional or reckless violation of the Act or this Part shall constitute a Class A misdemeanor. (Section 12 of the Act)*
- f) Sections 697.110, 697.120, 697.130 and 697.140 *shall not apply to eligibility and coverage requirements established by a health maintenance organization nor to any insurance company, fraternal benefit society, or other insurer regulated under the Illinois Insurance Code. (Section 15.1 of the Act)*

(Source: Amended at 38 Ill. Reg. \_\_\_\_\_, effective \_\_\_\_\_)

SUBPART E: MISCELLANEOUS PROVISIONS

**Section 697.400 Notification of School Principals (Repealed)**

- a) ~~*Whenever a child of school age is reported to the Department or a local health department with a confirmed HIV infection, the Department or local health authority shall give prompt (within three working days) and confidential notice of the identity of the child to the principal of the school in which the child is enrolled. If the child is enrolled in a public school, the principal shall disclose the identity of the child to the superintendent of the school district in which the child resides. (Section 2a of the Communicable Disease Prevention Act) School age is defined as between ages 5 and 21 by Section 10-20.12 of the School Code and between ages 3 and 21 for handicapped children by the Education for All*~~

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~~Handicapped Children Act. Diagnosed cases and laboratory results are reported to the Department in accordance with the Control of Sexually Transmissible Infections Code. If the child resides in a county or city governed by a Local Health authority, notification shall be the responsibility of the Local Health authority. In all other cases, notification shall be the responsibility of the Department. The Local Health authority or the Department shall offer assistance to the principal concerning HIV, the availability of counseling and training, and guidelines for management of the child in the classroom.~~

- b) ~~Upon receipt of the notice, the principal may, as necessary, such as when a student needs medical attention or must take medication during school attendance, or when the student's clinical condition necessitates other services, disclose the identity of an infected child to the school nurse at that school, the classroom teachers in whose classes the child is enrolled, and those persons who, pursuant to federal or State law, are required to decide the placement or educational program of the child. In addition, the principal may inform such other persons as may be necessary, in the opinion of the principal, that an infected child is enrolled at that school so long as the child's identity is not revealed. (Section 2a of the Communicable Disease Prevention Act)~~
- e) ~~No person to whom the child's identity is disclosed may disclose the information to any other person except as permitted by law (see Sections 9 and 10 of the Act).~~

(Source: Repealed at 38 Ill. Reg. \_\_\_\_\_, effective \_\_\_\_\_)