

DEPARTMENT OF PUBLIC HEALTH

NOTICE OF PROPOSED AMENDMENTS

- 1) Heading of the Part: Perinatal HIV Prevention Code
- 2) Code Citation: 77 Ill. Adm. Code 699
- 3)

<u>Section Numbers</u> :	<u>Proposed Action</u> :
699.10	Repeal
699.20	Amend
699.30	Amend
699.100	Amend
699.200	Amend
699.300	Amend
699.400	Amend
699.410	Amend
699.420	Amend
699.500	New
699.510	New
699.520	New
699.APPENDIX A	Repeal
699.ILLUSTRATION A	Repeal
699.ILLUSTRATION B	Repeal
- 4) Statutory Authority: Implementing and authorized by the Perinatal HIV Prevention Act [410 ILCS 335] and Sections 2310-10 and 2310-580 of the Civil Administrative Code of Illinois [20 ILCS 2310/2310-10 and 2310-580]
- 5) A Complete Description of the Subjects and Issues Involved: The Perinatal HIV Prevention Code will be updated and revised to correspond with new laboratory testing methodologies approved by the U.S. Food and Drug Administration, provide requirements for follow-up services during the perinatal period, and address the protection of confidential information. The sample written informed consent forms are repealed because the Act no longer requires that informed consent be provided in a written format.

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*.

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- 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
- 9) Does this rulemaking contain incorporations by reference? No
- 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 mandates 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:

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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:

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- A) Types of small businesses, small municipalities and not for profit corporations affected: None
 - 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: 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 699

PERINATAL HIV PREVENTION CODE

SUBPART A: GENERAL PROVISIONS

Section

- 699.10 General Applicability (~~Repealed~~)
- 699.20 Definitions
- 699.30 Referenced Materials

SUBPART B: HIV PERINATAL COUNSELING AND TESTING

Section

- 699.100 Perinatal Counseling and Testing

SUBPART C: HIV COUNSELING AND TESTING IN LABOR AND DELIVERY

Section

- 699.200 HIV Counseling and Testing in Labor and Delivery

SUBPART D: COUNSELING AND TESTING POST-DELIVERY

Section

- 699.300 HIV Testing of a Newborn Infant Post-Delivery

SUBPART E: HIV TESTING AND TEST RESULT DISCLOSURE

Section

- 699.400 Approved HIV Tests
- 699.410 ~~Written~~-Informed Consent for HIV Testing
- 699.420 Test Result Disclosure

SUBPART F: HIV REPORTING

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Section699.500 Telephone Reporting of Positive HIV Tests699.510 Reporting of Perinatal HIV Exposure699.520 Monthly Reporting of Data699.APPENDIX A Sample HIV Testing Forms (Repealed)699.ILLUSTRATION A Sample Written Refusal Form for Testing Newborn Infants
(Repealed)699.ILLUSTRATION B Sample Written Informed Consent to Perform a Rapid HIV
Test in the Labor and Delivery Setting (Repealed)

AUTHORITY: Implementing and authorized by the Perinatal HIV Prevention Act [410 ILCS 335] and Sections 2310-10 and 2310-580 of the Civil Administrative Code of Illinois [20 ILCS 2310/2310-10 and 2310-580].

SOURCE: Adopted at 30 Ill. Reg. 9345, effective May 4, 2006; amended at 36 Ill. Reg. _____, effective _____.

SUBPART A: GENERAL PROVISIONS

Section 699.10 General Applicability (Repealed)

- a) ~~This Part implements the Perinatal HIV Prevention Act, which concerns the prevention of vertical transmission of HIV infection from mother to newborn infant during pregnancy or labor and delivery. Subpart A includes general provisions that apply to all Sections of the Part, such as definitions and administrative hearing rules.~~
- b) ~~Subpart B concerns counseling and testing of pregnant women for the presence of antibodies to the human immunodeficiency virus (HIV). These provisions set forth the information that must be included in counseling by a health care professional; the written informed consent that a health care professional must obtain prior to performing an HIV test; and requirements for documentation of testing or test results in accordance with the Perinatal HIV Prevention Act and the AIDS Confidentiality Act.~~
- e) ~~Subpart C provides for counseling and rapid HIV antibody testing in labor and delivery; the requirement for written informed consent for testing the pregnant~~

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~~woman; and post-delivery follow-up services for women who test positive for HIV.~~

- d) ~~Subpart D provides for testing of a newborn infant when the mother does not have a documented HIV test result during the current pregnancy. Testing of the newborn infant is required upon delivery or within 48 hours after the newborn infant's birth, unless the parent or legally authorized representative provides written refusal for HIV testing of the newborn infant. Referral to post-delivery follow-up services for newborn infants who test positive for HIV is also required.~~

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

Section 699.20 Definitions

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

"Act" means the Perinatal HIV Prevention Act [410 ILCS 335].

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

"Antiretroviral Preventive Treatment" means a well-established method of preventing vertical HIV transmission.

"Department" means the ~~Illinois~~ Department of Public Health. ~~(Section 3(a) of the AIDS Confidentiality Act)~~ (Section 5 of the Act)

"Health Care Facility" or "Facility" means any hospital or other institution that is licensed or otherwise authorized to deliver health care services. (Section 5 of the Act)

"Health Care Professional" means a physician licensed to practice medicine in all its branches, a physician assistant who has been delegated the provision of health services by his or her supervising physician, or an advanced practice registered nurse who has a written collaborative agreement with a collaborating physician that authorizes the provision of health services. (Section 5 of the Act)

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"Health Care Services" means any prenatal medical care or labor or delivery services to a pregnant woman and her newborn infant, including hospitalization.
(Section 5 of the Act)

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

"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 (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.

"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 ~~lacking decisional capacity~~~~the apparent inability to understand or communicate with the health care provider~~) as determined by the health care ~~professional~~~~provider~~ seeking ~~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, legally authorized representative or other court-appointed personal representative, except as limited by Section 9(k) of the

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AIDS Confidentiality Act providing limitations on the ability of a parent or legal guardian to receive the child's test results, and Sections 4 and 5 of the Consent by Minors to Medical Procedures Act [410 ILCS 210] regarding release of test results involving a sexually transmitted infection,

Legal guardian or other court-appointed personal representative,

Adult next-of-kin.

For a living or deceased adult age 18 or over:

Agent authorized by durable power of attorney for health care,

Legal~~Legally authorized representative~~ or other court-appointed personal representative,

Spouse or person in a civil union,

Adult children,

Parent,

Adult next-of-kin.

"Perinatal" means ~~of,~~ relating to, or during~~being~~ the period around childbirth, especially the five months before and one month after birth.

"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 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 60 minutes~~a short interval of time (under 60 minutes)~~.

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"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.

~~"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 AIDS Confidentiality Act)~~

"Vertical Transmission" means transmission of a pathogen such as HIV from mother to fetus or baby during pregnancy or birth.

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

Section 699.30 Referenced Materials

The following materials are referenced in this Part:

- a) Illinois Statutes
 - 1) AIDS Confidentiality Act [410 ILCS 305]
 - 2) Perinatal HIV Prevention Act [410 ILCS 355]
 - 3) Medical Practice Act of 1987 [225 ILCS 60]-
 - 4) ~~The~~ Civil Administrative Code of Illinois [20 ILCS 2310]
 - 5) Consent by Minors to Medical Procedures Act [410 ILCS 210]
- b) Illinois Administrative Rules
 - HIV/AIDS Confidentiality and Testing Code (77 Ill. Adm. Code 697)

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

SUBPART B: HIV PERINATAL COUNSELING AND TESTING

Section 699.100 Perinatal Counseling and Testing

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- a) *Every health care professional who provides health care services to a pregnant woman shall, unless she has already been tested during the current pregnancy, provide the woman with HIV counseling, as described in this Section, and shall test her for offer HIV testing as early in the pregnancy as possible, unless she refuses unless she has already received an HIV test during the current pregnancy. (Section 10(a) of the Act)*
- b) *For women at continued risk of exposure to HIV infection in the judgment of the health care professional, a repeat test should be recommended offered late in pregnancy or at the time of labor and delivery. (Section 10(a) of the Act)*
- c) *HIV counseling and testing or refusal offer of testing shall be documented in the woman's medical record. (Section 10(b) of the Act) ~~Any testing or test results shall be conducted and documented in accordance with the AIDS Confidentiality Act and the HIV/AIDS Confidentiality and Testing Code.~~*
- d) *Any testing or test results shall be conducted in accordance with the AIDS Confidentiality Act and the HIV/AIDS Confidentiality and Testing Code and shall be documented in accordance with the AIDS Confidentiality Act and the HIV/AIDS Confidentiality and Testing Code in the woman's medical record. (Section 10(b) of the Act)*
- e) *All HIV counseling must be provided in accordance with the AIDS Confidentiality Act and must include ~~shall include~~, at minimum, the following information:*
- 1) *For the health of the pregnant woman, the voluntary nature of the testing, the benefits of HIV testing for the pregnant woman, including the prevention of transmission and the requirement that the HIV testing be performed unless she refuses and the methods by which she can refuse;*
 - 2) *The benefit of HIV testing for herself and the newborn infant, including interventions to prevent HIV transmission;*
 - 3) *The side effects of interventions to prevent HIV transmission;*

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- 4) *The statutory confidentiality provisions that relate to HIV and ~~AIDSAIDS~~ testing;*
- 5) *The requirement for mandatory testing of the newborn if the mother's HIV status is unknown at the time of delivery; The voluntary nature of the testing, including the opportunity to refuse testing of a newborn infant in writing; (Section 10 of the Act)*
- 6) *An explanation of the test, including its purpose, limitations, and the meaning of its results;*
- 7) *An explanation of the procedures to be followed;*
- 8) *The availability of additional or confirmatory testing, if appropriate. Counseling may be provided in writing, verbally, or by video, electronic, or other means. The woman must be offered an opportunity to ask questions about testing and to decline testing for herself. (Section 10(d) of the Act)*
- f) *Information shall also be provided concerning the following:*
 - 16) ~~Information about~~ HIV infection and HIV transmission;
 - 7) ~~Information about the meaning of the test and test results, such as: the purpose, potential uses, and limitations of the test, rapid HIV test, rapid HIV test results and the need for confirmatory testing;~~
 - 28) Methods of preventing HIV transmission; and
 - 39) ~~The Information about the~~ *availability of referrals for further information or counseling (Section 5 of the AIDS Confidentiality Act).*
- e) *~~HIV testing shall be provided with the woman's written informed consent. "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 or any element of force, fraud, deceit, duress or other form of constraint or coercion, which entails at least the following:~~*

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- 1) ~~A fair explanation of the test, including its purpose, potential uses and limitations and the meaning of its results;~~
- 2) ~~A fair explanation of the procedures to be followed, including the voluntary nature of the test; the right to withdraw consent at any time; the right to anonymity to the extent provided by the AIDS Confidentiality Act 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 AIDS Confidentiality Act)~~

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

SUBPART C: HIV COUNSELING AND TESTING IN LABOR AND DELIVERY

Section 699.200 HIV Counseling and Testing in Labor and Delivery

- a) A health care facility providing medical care for labor or delivery services to a pregnant woman and her newborn infant shall develop and follow written policies and procedures concerning the delegation of the responsibilities for carrying out the counseling and testing requirements of Subparts C and D of this Part. These policies and procedures shall be provided to the Department upon request. Delegation of responsibilities shall be in accordance with other personnel policies of the facility and the Act.
- b) ~~Every health care professional or facility that cares for a pregnant woman during labor or delivery shall, unless she has already been tested during the current pregnancy and HIV test results are already documented in the woman's medical record, provide the woman with HIV counseling and offer rapid HIV testing unless she refuses, in accordance with Section 699.100(c) and (d) of this Part. HIV testing shall be provided with the woman's, if HIV test results are not already documented in the woman's medical record. HIV testing shall be provided with the woman's written informed consent in accordance with Section 699.100(e) of this Part. (Section 10(b) of the Act)~~
- e) ~~No counseling or offer of testing is required if the woman's HIV status during the current pregnancy is already provided in her medical record. (Section 10 of the Act)~~

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- ~~c~~d) *The counseling and testing or refusal offer of testing shall be documented in the woman's labor and delivery medical record. ~~Any testing or test results shall be conducted in accordance with the AIDS Confidentiality Act and the HIV/AIDS Confidentiality and Testing Code and shall be documented in accordance with the AIDS Confidentiality Act and the HIV/AIDS Confidentiality and Testing Code in the woman's medical record.~~ (Section 10(b) of the Act)*
- d) *The health care facility shall adopt a policy that provides that as soon, as possible within medical standards after the infant's birth, the mother's HIV test result, if available, shall be noted in the newborn infant's medical record. It shall also be noted in the newborn infant's medical record if the mother's HIV test result is not available because she has not been tested or has declined testing. (Section 10(b) of the Act)*
- e) *Any testing or test results shall be conducted in accordance with the AIDS Confidentiality Act and the HIV/AIDS Confidentiality and Testing Code and shall be documented in accordance with the AIDS Confidentiality Act and the HIV/AIDS Confidentiality and Testing Code in the woman's medical record. (Section 10(b) of the Act)*
- fe) In addition to the counseling information required in Section 699.100(d) ~~of this Part~~, when disclosing a positive result of a rapid HIV test to a pregnant woman, health care professionals shall provide the woman with post-delivery follow-up referrals to physicians or facilities with experience in providing services to women with HIV.

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

SUBPART D: COUNSELING AND TESTING POST-DELIVERY

Section 699.300 HIV Testing of a Newborn Infant Post-Delivery

- a) *Every health care professional or facility caring for a newborn infant shall, upon delivery or as soon as possible within medical standards after the infant's birth, provide counseling as described in Section 10(d) of the Act to the parent or guardian of the infant and perform rapid HIV testing on the infant, when the HIV status of the infant's mother is unknown. Immediately after birth and within 48*

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~~hours after birth, every health care professional or facility shall provide to the parent or legally authorized representative an explanation that the newborn infant will be HIV tested when the mother's HIV status is not documented, unless there is a written refusal for HIV testing by the parent or legally authorized representative of the newborn infant. (Section 10(c) of the Act)~~

- b) ~~The health care professional or facility shall document in the woman's medical record that counseling and the offer of HIV testing for the newborn infant were given in accordance with Section 699.100(c) and (d) of this Part, and whether the parent or legally authorized representative provided written refusal for HIV testing for the newborn infant. (Section 10(c) of the Act)~~
- b1) The health care professional providing the positive result of an HIV test on a newborn infant shall provide ~~to~~ the parent or legally authorized representative with an explanation of antiretroviral preventive treatment for HIV-exposed newborn infants.
- 2) ~~When the newborn infant has tested positive, the health care professional providing information on antiretroviral preventive treatment for the newborn infant shall explain to the mother how the test detects HIV antibodies, offer HIV risk counseling, encourage HIV testing for the mother, and provide referrals to physicians or facilities that have experience treating women and children with HIV.~~
- c) When the newborn infant has tested positive, the health care professional providing information on antiretroviral preventive treatment for the HIV-exposed newborn infant shall explain to the mother how the test detects maternal HIV infection, offer HIV risk counseling, encourage HIV testing for the mother, and provide referrals to physicians or facilities that have experience treating women and children with HIV.
- de) *Consent for testing of a newborn infant shall be presumed when a health care professional or health care facility seeks to perform a test on a newborn infant whose mother's HIV status is not known, provided that the counseling required under Section 10(d) of the Act, Section 699.100(d) of this Part and the AIDS Confidentiality Act and subsection (d) of this Section has taken place and the newborn infant's parent or legally authorized representative has not indicated in*

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~~writing that he or she refuses to allow the newborn infant to receive HIV testing.
(Section 10(e) of the Act)~~

~~ed) Counseling required in this Subpart shall include the elements required in Section 699.100(d). Counseling Requirements~~

- ~~1) *Counseling required under this Subpart must be provided in accordance with the AIDS Confidentiality Act and must include the following:*
 - ~~A) *The benefits of HIV testing for the pregnant woman, including the prevention of transmission.*~~
 - ~~B) *The benefit of HIV testing for the newborn infant, including interventions to prevent HIV transmission.*~~
 - ~~C) *The side effects of interventions to prevent HIV transmission.*~~
 - ~~D) *The statutory confidentiality provisions that relate to HIV and AIDS testing.*~~
 - ~~E) *The voluntary nature of the testing, including the opportunity to refuse testing in writing. (Section 10(d) of the Act)*~~~~
- ~~2) *The requirements for counseling and testing must be provided in accordance with the AIDS Confidentiality Act, with the exception of the requirement of consent for testing of newborn infants. (Section 10(e) of the Act)*~~
- ~~3) *Information about HIV infection and HIV transmission.*~~
- ~~4) *Information about the meaning of the test and test results, such as: the purpose, potential uses, and limitations of the test, rapid HIV test, rapid HIV test results and the need for confirmatory testing.*~~
- ~~5) *Methods of preventing HIV transmission.*~~
- ~~6) *Information about the availability of referrals for further information or counseling. (Section 5 of the AIDS Confidentiality Act)*~~

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

SUBPART E: HIV TESTING AND TEST RESULT DISCLOSURE

Section 699.400 Approved HIV Tests

HIV ~~antibody~~ testing shall be completed in accordance with Section 697.100 of the 77 Ill. Adm. Code 697.100 (HIV/AIDS Confidentiality and Testing Code).

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

Section 699.410 ~~Written~~ Informed Consent for HIV Testing

No person may order an HIV test for a pregnant woman without first receiving the documented~~written~~ informed consent of the subject of the test or subject's legally authorized representative. (Section 4 of the AIDS Confidentiality Act)

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

Section 699.420 Test Result Disclosure

Release of HIV test results shall be as described in 77 Ill. Adm. Code 697.140 ~~77 Ill. Adm. Code 697.140~~ (HIV/AIDS Confidentiality and Testing Code). Positive results from rapid HIV ~~antibody~~ tests may be released in accordance with Section 697.100 of that Code ~~77 Ill. Adm. Code 697.100~~.

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

SUBPART F: HIV REPORTING**Section 699.500 Telephone Reporting of Positive HIV Tests**

- a) Health care facilities shall report a preliminary positive rapid HIV test in a delivering mother or her infant within 24 hours after birth by calling the 24/7 Perinatal HIV Hotline and by submitting a Preliminary Positive Data Collection Report.

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- b) Health care facilities shall report a preliminary positive rapid HIV test in a pregnant outpatient by calling the 24/7 Perinatal HIV Hotline as soon as possible.
- c) Health care facilities reporting a preliminary positive HIV test result shall conduct supplemental testing and communicate the results by telephone to the 24/7 Perinatal HIV Hotline.

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

Section 699.510 Reporting of Perinatal HIV Exposure

- a) Health care facilities shall report a case of perinatal HIV exposure using the Department's Pediatric HIV/AIDS Confidential Case Report for a person under age 13 when caring for a newborn:
 - 1) Whose mother is confirmed to be HIV positive prior to labor and delivery;
 - 2) Whose mother has a rapid HIV test result that is preliminary positive at labor and delivery, and the supplemental test results are positive; or
 - 3) Who has a rapid HIV test result that is preliminary positive at delivery, and the supplemental test results are positive.
- b) If, after 18 months from the date that the report was submitted, a newborn infant is determined to not have HIV or AIDS, the Department shall remove the newborn infant's name from all reports, records and files collected or created.

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

Section 699.520 Monthly Reporting of Data

- a) Health care facilities shall report monthly aggregate statistics to the Department, including, but not be limited to, the number of:
 - 1) known positive pregnant women presenting for delivery;
 - 2) pregnant women rapidly tested for HIV;

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- 3) newborn infants rapidly tested for HIV;
 - 4) preliminary HIV-positive women;
 - 5) preliminary HIV-exposed newborn infants; and
 - 6) mothers and infants successfully linked to ongoing medical care and case management services.
- b) Aggregate monthly data shall be reported on the Perinatal Rapid HIV Testing Monthly Report form provided by the Department, and the report shall be submitted by the tenth day of the following month.
- c) Health care facilities shall complete a preliminary positive data report for every case of a preliminary positive HIV result in a mother or newborn infant. Data are reported on the Preliminary Positive Rapid Data Collection form provided by the Department. The report shall be submitted immediately following the identification of the preliminarily positive test result and resent after supplemental test results are available.

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

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Section 699.APPENDIX A Sample Rapid HIV Testing Forms (Repealed)

Section 699.ILLUSTRATION A Sample Written Refusal Form for Testing Newborn Infants (Repealed)

~~WRITTEN REFUSAL OF RAPID HIV ANTIBODY TESTING FOR A NEWBORN INFANT~~

Test Subject or Number: _____

Date: _____
Time: _____

~~As a parent or legal guardian of a newborn infant, I am not giving my permission for a Food and Drug Administration (FDA) approved test to detect whether my newborn infant has antibodies to HIV (human immunodeficiency virus).~~

~~I understand that:~~

~~The human immunodeficiency virus (HIV) is the virus that causes AIDS.~~

- ~~•One way in which HIV is spread is by sexual intercourse, so all sexually active women are potentially at risk for HIV infection.~~
- ~~•HIV can be passed from a mother to her baby during pregnancy, at delivery, and through breastfeeding.~~
- ~~•If I have HIV, it is a serious illness that can affect my health and the health of my baby.~~
- ~~•HIV antibody test results are confidential.~~

~~I have been counseled about HIV, including:~~

- ~~•The potential benefit of HIV testing for my newborn infant, including interventions to prevent transmission of infection from mother to baby;~~
- ~~•Information about HIV infection and HIV transmission;~~

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- ~~Information about the meaning of the HIV test and the test results;~~
- ~~The side effects of interventions to prevent HIV transmission;~~
- ~~Information about the availability of referrals and further counseling;~~
- ~~The voluntary nature of the HIV testing, including the opportunity to refuse, in writing, testing of the newborn infant; and~~
- ~~The confidentiality provisions that relate to HIV/AIDS testing.~~

~~**I understand** that I can refuse HIV testing of my newborn infant. I understand that testing should occur immediately after birth, but no later than 48 hours after birth. I understand that if my newborn infant receives medication no later than 48 hours after birth, the risk of transmission of HIV would be lowered. I understand that delaying testing to a later time will reduce or eliminate the chance that medication can be used to prevent my baby from becoming HIV infected.~~

~~**I understand** that I have received a fair explanation of:~~

- ~~The HIV test procedures to be followed;~~
- ~~My right to withdraw my consent to an HIV test at any time;~~
- ~~The right to anonymity to the extent provided by law with respect to participation in the HIV test and disclosure of test results, and the right to keep confidential information that identifies the subject of the HIV test and the test results.~~

~~**I understand** that if my newborn infant is tested for HIV, the results of the tests are placed in my newborn infant's record and reported to his/her health care provider, and positive results are reported to the Illinois Department of Public Health. Under Illinois law, confidential HIV information can be given only to people to whom I allow it to be given by my written approval, or to people who need to know my newborn infant's HIV status in order to provide medical care and services, including an authorized agent or employee of a health facility or health care provider, if the health facility or provider is authorized to obtain test results; those who are exposed to my newborn infant's blood/body fluids in the course of their employment; and organizations that review the health care services I receive. The law also allows my newborn infant's HIV information to be released under certain limited circumstances to persons whom I~~

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~~may designate through an authorization, to my legal representative, to my spouse, to the parent of the child, to public health officials as required by law, for payment for care and treatment, and as required for a temporary caretaker of a child taken into protective custody by the Department of Children and Family Services. The results also will be provided to the State and local health department to use this information to track the disease and to better plan prevention, health care, and other services.~~

~~I understand and agree that my REFUSAL of testing will be placed in my medical record. In addition, I understand that I may withdraw my REFUSAL of HIV testing for my newborn infant at any point in time.~~

<p>I understand that HIV may be transmitted from me to my newborn infant during labor and delivery. I understand that if I refuse HIV testing for my newborn infant, he/she will not be able to promptly receive medication that lowers the risk of his/her becoming HIV infected. I understand that if HIV has already been transmitted to my child, not performing the test means he/she will not receive proper treatment. Delaying testing to a later time will reduce or eliminate the chance that medication can be used to prevent my child from becoming HIV infected. I understand that HIV infection causes serious illnesses and these illnesses could result in my newborn's death.</p> <p>With the information presented above having been completely and clearly explained to me, and all of my questions having been answered, I refuse to authorize testing of my newborn infant for HIV.</p>

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

~~_____
Date~~

~~_____
Health Care Professional/Facility Witness~~

~~_____
Date~~

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

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Section 699.APPENDIX A Sample HIV Testing Forms **(Repealed)**

Section 699.ILLUSTRATION B Sample Written Informed Consent to Perform a Rapid HIV Test in the Labor and Delivery Setting **(Repealed)**

~~WRITTEN INFORMED CONSENT TO PERFORM A RAPID
HIV TEST IN THE LABOR AND DELIVERY SETTING~~

Test Subject or
Number: _____ Date: _____
Time: _____

~~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 rapid HIV testing is to show whether you are infected with HIV, the virus that causes AIDS.~~

~~If you are HIV infected, rapid HIV testing will allow you to receive immediate medication during labor and delivery to reduce the risk of transmitting HIV to your newborn, and will allow your baby to receive the same medication immediately after birth.~~

~~Before you consent to be tested for HIV, speak to your health care provider about:~~

- ~~•How HIV can be passed from person to person and mother to baby;~~
- ~~•Medication that may prevent the transmission of HIV from mother to baby;~~
- ~~•Illinois law that requires all newborn infants to be tested for HIV after birth if the mother's HIV status is unknown, unless the parent provides a written refusal; and~~

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~~•The meaning of preliminary HIV test results and how a positive HIV test 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.~~
- ~~•One of the ways in which HIV is spread is by sexual intercourse, so all sexually active women are potentially at risk for HIV infection.~~
- ~~•HIV can be passed from a mother to her baby during pregnancy, at delivery, and through breastfeeding;~~
- ~~•If I have HIV, it is a serious illness that can affect my health and the health of my baby.~~
- ~~•HIV antibody test results are confidential, and the law protects me from discrimination.~~

~~If I am found to be HIV infected, treatment is available to reduce the risk that HIV will be~~

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~~transmitted to my baby:~~

- ~~•If I have not yet delivered my baby, I may receive medication as soon as possible to reduce the chance of passing the virus to my baby.~~
- ~~•My baby may receive medication that reduces the risk of his/her becoming HIV infected.~~
- ~~•In many cases, medications prevent the risk of transmission of HIV. If these medications are given to me during labor and delivery, or to my newborn infant immediately after birth, the chance that my baby will be HIV infected is significantly reduced.~~
- ~~•If treatment is started, my health care provider will discuss with me any consequences of taking the medication.~~

~~**I understand** that a preliminary positive result does not mean that I have AIDS, but that my blood may have been exposed to the human immunodeficiency virus, and antibodies to that virus may be present in my body. I understand that if my test results are positive, I will be offered HIV counseling.~~

~~**I understand** that HIV 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 test that I am consenting to take will provide me and my health care provider with results within 12 hours:~~

- ~~•If I have the rapid HIV test, I will be given the results no later than 12 hours after my blood is drawn.~~
- ~~•If the 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.~~
- ~~•A preliminary positive HIV test result means there is a possibility that I am HIV infected and that my baby may have been exposed to HIV. A second test, to confirm a preliminary positive HIV test result, will be done.~~
- ~~•I understand that if my preliminary test result is positive, I still may not have HIV~~

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~~infection (false positive test results can occur), but it may be best to start treatment to help prevent the transmission of infection to my baby while I wait for the confirmatory test result.~~

~~All preliminary positive test results will be confirmed:~~

- ~~•If the confirmatory HIV test result is negative, I will immediately be taken off of medication that was started to help prevent transmission of HIV from me to my baby.~~
- ~~•If the confirmatory test is positive, any medication that was given to help to prevent transmission of HIV from me to my baby will be continued.~~
- ~~•If the confirmatory test is positive, I will be referred to a physician for my own ongoing medical care.~~

~~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.~~

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

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

~~I understand that a preliminary positive result from my rapid HIV antibody test will be released to designated health care professionals to provide necessary treatment to prevent HIV transmission from mother to child.~~

~~I agree that if the result of my HIV test is preliminary positive or if the result of my rapid HIV antibody test is confirmed positive, I may be referred to another health care provider for follow-up testing and care. I consent to the release of my medical information, including my HIV test results and contact information, to that provider for the purpose of follow-up testing and care.~~

If I choose not to have a rapid HIV test, ~~I understand that:~~

- ~~• I may be positive for HIV, which is a serious illness that can affect my health and the health of my baby.~~
- ~~• I may be positive for HIV and may not receive appropriate treatment for this serious illness.~~
- ~~• I may be HIV positive and my child is at risk of my transmitting HIV to him/her through labor and delivery. As a result, my child could also be HIV positive. I understand that HIV in my child is a serious illness (see above) and this illness (see above) could result in my newborn infant's death, unless my newborn infant is tested and treated.~~

~~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; the medical risks if I refuse; 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.~~

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

~~Date~~

~~Facility/Provider Witness~~

Placement of My Medical Information in My Newborn Infant's Medical Record

~~I understand that, in order to effectively treat my newborn infant, the results of the tests and my HIV status should be placed in my newborn infant's medical record. If this information is placed in my newborn infant's medical record, I understand that my test results and my HIV status in the newborn infant's medical record may be disclosed to those providing care and treatment to my newborn infant. I also understand that my information in my newborn infant's medical record may be disclosed to my spouse; to a legally authorized representative; to a person whom I have designated through an authorization (my written authorization permitting him or her to release my information); to my newborn infant at a later time; or to a court or other entity that has the legal authority to have access to my newborn infant's medical record.~~

~~YES. I consent to have my HIV test results and my HIV status placed in my newborn infant's medical record.~~

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

~~Date~~

~~NO. I do not want my HIV test results and my HIV status placed in my newborn infant's medical record. I understand that this may adversely affect medical treatment for my newborn infant.~~

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

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Date

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