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**TITLE 410 INDIANA STATE DEPARTMENT OF  
HEALTH**

**Proposed Rule**  
LSA Document #03-161

**DIGEST**

Adds 410 IAC 1-7 to establish procedures subsequent to the testing of pregnant women for HIV and standards regarding the provision of information concerning HIV to women who are pregnant, before delivery, at delivery, and after delivery. Effective 30 days after filing with the secretary of state.

**410 IAC 1-7**

SECTION 1. 410 IAC 1-7 IS ADDED TO READ AS FOLLOWS:

**Rule 7. HIV Counseling and Testing of Pregnant Women**

**410 IAC 1-7-1 Applicability**

**Authority:** IC 16-41-6-11

**Affected:** IC 16-41-6

**Sec. 1.** The definitions in this rule apply throughout this rule. *(Indiana State Department of Health; 410 IAC 1-7-1)*

**410 IAC 1-7-2 “AIDS” defined**

**Authority:** IC 16-41-6-11

**Affected:** IC 16-41-6

**Sec. 2.** “AIDS” means acquired immune deficiency syndrome. *(Indiana State Department of Health; 410 IAC 1-7-2)*

**410 IAC 1-7-3 “Department” defined**

**Authority:** IC 16-41-6-11

**Affected:** IC 16-41-6

**Sec. 3.** “Department” means the Indiana state department of health. *(Indiana State Department of Health; 410 IAC 1-7-3)*

**410 IAC 1-7-4 “HIV” defined**

**Authority:** IC 16-41-6-11

**Affected:** IC 16-41-6

**Sec. 4.** “HIV” means human immunodeficiency virus. *(Indiana State Department of Health; 410 IAC 1-7-4)*

**410 IAC 1-7-5 “HIV medical services program” defined**

**Authority:** IC 16-41-6-11

**Affected:** IC 16-41-6

**Sec. 5.** “HIV medical services program” means those medical and pharmaceutical services available to eligible HIV positive persons provided by the department through the support of state and federal funding. *(Indiana State Department of Health; 410 IAC 1-7-5)*

**410 IAC 1-7-6 “Provider” defined**

**Authority:** IC 16-41-6-11

**Affected:** IC 16-41-6; IC 16-18-2-295

**Sec. 6. “Provider” has the meaning set forth in IC 16-18-2-295. (Indiana State Department of Health; 410 IAC 1-7-6)**

**410 IAC 1-7-7 Provider’s responsibilities to pregnant women who have been tested for HIV**

**Authority:** IC 16-41-6-11

**Affected:** IC 16-41-6

**Sec. 7. (a) A provider, or his or her designee, must deliver the following:**

- (1) The test results for HIV infected and HIV uninfected patients in a direct, straightforward, and confidential manner.**
- (2) The results at the earliest possible encounter after testing.**
- (3) The results face-to-face for HIV infected patients.**

**(b) If the test results positive, the treating provider, or his or her designee, must do the following:**

- (1) Explain the side effects of any treatment for HIV in a direct, straightforward, confidential manner.**
- (2) Discuss pros and cons of initiation of drug therapy.**
- (3) Discuss treatment recommendations based on the U.S. Public Health Service Task Force recommendation 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, MMWR 51, RR-18.**

*(Indiana State Department of Health; 410 IAC 1-7-7)*

**410 IAC 1-7-8 Pregnant woman on a waiting list for HIV medical services**

**Authority:** IC 16-41-6-11

**Affected:** IC 16-41-6-5; IC 16-41-6-6

**Sec. 8. (a) A pregnant woman must have a complete application for the HIV medical services program on file with the department.**

**(b) A pregnant woman who meets all the qualifications to participate in the HIV medical services program and tests positive under IC 16-41-6-5 or IC 16-41-6-6 shall be given first priority on a waiting list for the program if a waiting list exists for the HIV medical services program.**

**(c) A pregnant woman who tests positive under IC 16-41-6-5 or IC 16-41-6-6 may appeal her placement on a waiting list for HIV medical services by filing a written appeal with the department.**

**(d) The appeal shall be filed within fifteen (15) days of receipt of the notification of placement on a waiting list.**

**(e) The appeal will be reviewed by the state health commissioner, or his or her designee, who will also make the determination in the case within seventy-two (72) hours of receipt of all requested medical information and other pertinent documentation, as detailed by section 9 of this rule, necessary to determine the applicant’s eligibility for services.**

**(f) The appeal must include name, date of birth, and mailing address. (Indiana State Department of Health; 410 IAC 1-7-8)**

**410 IAC 1-7-9 Appeal of placement on a waiting list**

**Authority:** IC 16-41-6-11

**Affected:** IC 16-41-6

**Sec. 9. Applicants who appeal their placement on a waiting list for the HIV medical services program shall provide a signed physician’s statement confirming the following:**

- (1) The pregnancy.**
- (2) A HIV treatment regimen.**

*(Indiana State Department of Health; 410 IAC 1-7-9)*

#### **410 IAC 1-7-10 Information to the pregnant woman**

**Authority:** IC 16-41-6-11

**Affected:** IC 16-41-6

**Sec. 10. (a)** A provider, or his or her designee, shall provide the following to pregnant women at the appropriate times, which could include before delivery, at delivery, and after delivery:

**(1)** An explanation of the nature of AIDS and HIV that:

**(A)** is consistent with MMWR41, RR-17, and MMWR 43, RR12; and

**(B)** includes the following elements:

**(i)** HIV results in a defect in cell-mediated immune response causing increased susceptibility to opportunistic infections and certain rare cancers.

**(ii)** HIV is a virus that is transmitted from one (1) person to another through blood, semen, vaginal secretions, or breast milk.

**(iii)** HIV is a virus that, without treatment, aggressively destroys the immune system.

**(iv)** AIDS is a severe immunological disorder that can result from HIV.

**(2)** Information that it is unlawful to discriminate against persons living with HIV in areas of employment, housing, and provision of health care services. If the women believe that they have been discriminated against, they may contact the Indiana civil rights commission.

**(3)** Information that women who have tested positive for HIV or who have been diagnosed with AIDS are not to engage in high-risk activity (including sexual or needle-sharing contact, which has been demonstrated to transmit a dangerous communicable disease) without warning past, present, or future sexual or needle-sharing partners before engaging in that high-risk activity. Carriers who know of their status as a carrier of HIV or AIDS have a duty to warn or cause to be warned by a third party a person at risk, including a spouse of the last ten (10) years, of the following:

**(A)** The carrier's disease status.

**(B)** The need to seek health care, such as counseling and testing.

**(4)** Information about risk behaviors for HIV transmission that is consistent with MMWR50, RR19. It must include the following:

**(A)** High-risk activities refer to sexual or needle-sharing contact, which has been demonstrated to transmit HIV.

**(B)** HIV is known to be transmitted through blood, semen, vaginal secretions, and breast milk.

**(5)** Information about the risk of transmission through breastfeeding that is consistent with MMWR50, RR19, including that breastfeeding by an HIV positive woman carries a risk for transmission of the virus from mother to infant.

**(b)** The department will continue to be a resource for educational information and referral sources. *(Indiana State Department of Health; 410 IAC 1-7-10)*

#### **410 IAC 1-7-11 Notification to the pregnant woman**

**Authority:** IC 16-41-6-11

**Affected:** IC 16-41-6-4

**Sec. 11.** If the mother of a newborn infant has not had a test performed for HIV or if the mother has refused a test for the newborn infant to detect HIV or the antibody or antigen to HIV and a physician believes that testing the newborn infant is medically necessary, the physician overseeing the care of the newborn infant may order a confidential test for the newborn infant in order to detect HIV or the antibody or antigen to HIV under IC 16-41-6-4. The test must be ordered at the earliest feasible time not exceeding forty-eight (48) hours after the birth of the infant. The mother shall be notified of the test and the result of the test. *(Indiana State Department of Health; 410 IAC 1-7-11)*

#### **410 IAC 1-7-12 Obtaining consent**

**Authority:** IC 16-41-6-11

**Affected:** IC 16-41-6-2; IC 16-41-6-7

**Sec. 12. (a)** The provider shall follow the procedures for obtaining consent of the woman as detailed in IC 16-41-6-2.

**(b)** The provider shall inform the woman of her options under IC 16-41-6-7. *(Indiana State Department of Health; 410 IAC 1-7-12)*

**410 IAC 1-7-13 Post-test counseling procedures**

**Authority:** IC 16-41-6-11

**Affected:** IC 16-41-6

**Sec. 13.** Post-test counseling will be conducted in a direct, straightforward, confidential manner by the provider or his or her designee. *(Indiana State Department of Health; 410 IAC 1-7-13)*

**410 IAC 1-7-14 Referral procedures**

**Authority:** IC 16-41-6-11

**Affected:** IC 16-41-6

**Sec. 14.** The provider shall assess the patient's level of need and provide referrals to the appropriate services, which may include HIV-specific case management services. *(Indiana State Department of Health; 410 IAC 1-7-14)*

**410 IAC 1-7-15 Importance of immediate HIV medical care**

**Authority:** IC 16-41-6-11

**Affected:** IC 16-41-6

**Sec. 15.** Providers, or their designees, shall counsel the patient regarding the importance of immediate entry into medical care for the duration of the pregnancy. *(Indiana State Department of Health; 410 IAC 1-7-15)*

**410 IAC 1-7-16 Explanation of decreasing transmission of HIV during pregnancy**

**Authority:** IC 16-41-6-11

**Affected:** IC 16-41-6

**Sec. 16. (a)** Providers shall counsel that HIV can be transmitted to the fetus during pregnancy, and treatment can significantly decrease that transmission.

**(b)** Providers shall counsel, prior to delivery, that giving birth by cesarean section may decrease transmission of HIV to the child, especially when done in combination with medications, if the HIV test results are positive.

**(c)** Counseling on this matter shall be conducted in a direct, straightforward, confidential manner by the provider or his or her designee. *(Indiana State Department of Health; 410 IAC 1-7-16)*

**410 IAC 1-7-17 Incorporation by reference**

**Authority:** IC 16-41-6-11

**Affected:** IC 16-41-6

**Sec. 17. (a)** The following documents are hereby incorporated by reference:

**(1)** Centers for Disease Control and Prevention publication: MMWR 2001 Revised Guidelines for HIV Counseling, Testing, and Referral and Revised Recommendations for HIV Screening of Pregnant Women – United States, 2001, November 9, 2001, Volume 50, No. RR 19.

**(2)** Centers for Disease Control and Prevention publication: MMWR 2002 HIV Testing Among Pregnant Women-United States and Canada, 1998-2001, November 15, 2002, Volume 51RR45.

**(3)** Centers for Disease Control and Prevention publication: MMWR 2002 U.S. Public Health Service Task Force 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, November 22, 2002, Volume 51/RR18.

**(4)** Centers for Disease Control and Prevention publication: MMWR 2003 Advancing HIV Prevention: New Strategies for a Changing Epidemic-United States, 2003, April 18, 2003, Volume No. 15.

**(b)** All incorporated material is available for public review at the department.

**(c)** Copies of MMWR publications may be obtained from Centers for Disease Control and Prevention, MMWR Series, Mail Stop C-08, 1600 Clifton Road, N.E., Atlanta, Georgia 30333. *(Indiana State Department of Health; 410 IAC 1-7-17)*

***Notice of Public Hearing***

*Under IC 4-22-2-24, notice is hereby given that on March 23, 2004 at 2:00 p.m., at the Indiana State Department of Health Building, 2 North Meridian Street, Yoho Board Room, 3rd Floor, Indianapolis, Indiana the Indiana State Department of Health will hold a public hearing on a proposed new rule to establish procedures subsequent to the testing of pregnant women for HIV and standards regarding the provision of information concerning HIV to women who are pregnant, before delivery, at delivery, and after delivery. Copies of these rules are now on file at the Community and Family Health Services Commission at the Indiana State Department of Health, 2 North Meridian Street and Legislative Services Agency, One North Capitol, Suite 325, Indianapolis, Indiana and are open for public inspection.*

Gregory A. Wilson, M.D.  
State Health Commissioner  
Indiana State Department of Health