TITLE 410 INDIANA STATE DEPARTMENT OF HEALTH

Proposed Rule
LSA Document #11-458

DIGEST

Amends 410 IAC 1 to clarify the definitions, to clarify the information and counseling given to a pregnant patient, to clarify reasons for not offering a human immunodeficiency virus test, to add the rapid test, to remove documentation that must be noted in the pregnant patient's medical record, to add information that must be included on the confidential part of each birth certificate, to clarify provider's responsibilities to a pregnant patient, and to update references to the Indiana Code. Adds 410 IAC 1-6-7.1, newborn testing in the event of maternal refusal. Repeals 410 IAC 1-7-11, notification to the pregnant patient. Effective 30 days after filing with the Publisher.

410 IAC 1-6-3; 410 IAC 1-6-4; 410 IAC 1-6-5; 410 IAC 1-6-6; 410 IAC 1-6-7; 410 IAC 1-6-7.1; 410 IAC 1-7; 410 IAC 1-7-7; IAC 1-7-8; 410 IAC 1-7-10; IAC 1-7-11; 410 IAC 1-7-12; 410 IAC 1-7-13; 410 IAC 1-7-14; 410 IAC 1-7-15; 410 IAC 1-7-16

SECTION 3. 410 IAC 1-6-3 IS AMENDED TO READ AS FOLLOWS:

410 IAC 1-6-3 "Prenatal care provider" defined

Authority: IC 16-19-3-5
Affected: IC 25-22.5; IC 25-23; IC 25-27.5

Sec. 3. "Prenatal care provider" means:
(1) a physician licensed under IC 25-22.5;
(2) a registered nurse licensed under IC 25-23;
(3) a licensed practical nurse licensed under IC 25-23; ~~or~~
(4) an advanced practice nurse licensed under IC 25-23;
(5) a physician assistant licensed under IC 25-27.5; or
(6) a midwife licensed under IC 25-23;
who provides prenatal care within the scope of the provider's license.
(Indiana State Department of Health; 410 IAC 1-6-3; filed Feb 9, 1999, 5:13 p.m.: 22 IR 1971; readopted filed Jul 15, 2005, 8:00 a.m.: 28 IR 3661)

SECTION 4. 410 IAC 1-6-4 IS AMENDED TO READ AS FOLLOWS:

410 IAC 1-6-4 Human immunodeficiency virus information and counseling to a pregnant patient

Authority: IC 16-19-3-5
Affected: IC 16-41-6

Sec. 4. (a) The prenatal care provider primarily responsible for providing prenatal care to a pregnant patient shall ~~offer~~ **provide** human immunodeficiency virus (HIV) information and counseling to the pregnant patient. The information and counseling must include the following:
(1) A description of the methods of human immunodeficiency virus (HIV) transmission**, including breastfeeding.**
(2) A discussion of risk reduction behavior modifications, including ~~methods~~ **interventions** to reduce the risk of perinatal transmission.
(3) Referral information to other human immunodeficiency virus (HIV) prevention **testing** and psychosocial services. ~~, if appropriate, including anonymous and confidential test sites approved by the state department.~~

(b) A group practice, clinic, or hospital shall designate, in writing, a health care professional to implement this rule.

(c) A group practice, clinic, or hospital shall designate, in writing, a health care professional to implement this rule. *(Indiana State Department of Health; 410 IAC 1-6-4; filed Feb 9, 1999, 5:13 p.m.: 22 IR 1971; readopted filed Jul 15, 2005, 8:00 a.m.: 28 IR 3661)*

SECTION 5. 410 IAC 1-6-5 IS AMENDED TO READ AS FOLLOWS:

410 IAC 1-6-5 Reasons for not offering a human immunodeficiency virus test

Authority: IC 16-19-3-5
Affected: IC 16-41-6

Sec. 5. The prenatal care provider primarily responsible for providing prenatal care to a pregnant patient shall ~~offer~~ **obtain** ~~an *[sic., a]*~~ **a** human immunodeficiency virus (HIV) test to the **pregnant** patient unless:

(1) a positive human immunodeficiency virus (HIV) test result is already documented in the **pregnant** patient's medical record;

(2) the **pregnant** patient has acquired immune deficiency syndrome (AIDS) as diagnosed by a physician; **or**

(3) the pregnant patient refuses in writing a human immunodeficiency virus (HIV) test.

(Indiana State Department of Health; 410 IAC 1-6-5; filed Feb 9, 1999, 5:13 p.m.: 22 IR 1971; readopted filed Jul 15, 2005, 8:00a.m.: 28 IR 3661)

SECTION 6. 410 IAC 1-6-6 IS AMENDED TO READ AS FOLLOWS:

410 IAC 1-6-6 Human immunodeficiency virus test

Authority: IC 16-19-3-5
Affected: IC 16-41-6

Sec. 6. (a) In ~~offering~~ **providing** ~~an *[sic., a]*~~ **a** human immunodeficiency virus (HIV) test under section 5 of this rule, the prenatal care provider shall discuss the following with the pregnant patient:

(1) The purpose of the human immunodeficiency virus (HIV) test.

(2) The risk and benefits of the human immunodeficiency virus (HIV) test.

(3) ~~The voluntary nature of the human immunodeficiency virus (HIV) test.~~ **The test will be performed routinely, unless it is refused in writing.**

~~(b) If the pregnant patient voluntarily consents to human immunodeficiency virus (HIV) testing, the prenatal care provider shall arrange for human immunodeficiency virus (HIV) testing directly or by referral, including referral to anonymous and confidential test sites approved by the department.~~ **If the pregnant patient presents in labor with no documented human immunodeficiency virus (HIV) test on record, then a rapid test should be administered.**

(Indiana State Department of Health; 410 IAC 1-6-6; filed Feb 9, 1999, 5:13 p.m.: 22 IR 1971; readopted filed Jul 15, 2005, 8:00 a.m.: 28 IR 3661)

SECTION 7. 410 IAC 1-6-7 IS AMENDED TO READ AS FOLLOWS:

410 IAC 1-6-7 Documentation

Authority: IC 16-19-3-5; IC 16-41-6-11
Affected: IC 16-41-6

Sec. 7. (a) The prenatal care provider primarily responsible for providing prenatal care to a pregnant patient shall document in the **pregnant** patient's medical record that the prenatal care provider ~~offered~~ **provided** the following to the **pregnant** patient:

(1) Human immunodeficiency virus (HIV) information and counseling.

(2) ~~An *[sic., A]*~~ **A** human immunodeficiency virus (HIV) test.

~~(b) Documentation in the patient's medical record must include notation that the following was offered to the patient:~~

~~(1) A description of the methods of human immunodeficiency virus (HIV) transmission.~~

~~(2) A discussion of risk reduction behavior modifications, including methods to reduce the risk of perinatal transmission.~~

~~(3) Referral information to other human immunodeficiency virus (HIV) prevention and psychosocial services, if appropriate, including anonymous and confidential test sites approved by the department.~~

~~(4) Discussion of the purpose of the human immunodeficiency virus (HIV) test.~~

~~(5) Discussion of the risk and benefits of the human immunodeficiency virus (HIV) test.~~

~~(6) Discussion of the voluntary nature of the human immunodeficiency virus (HIV) test.~~

~~(7) Documentation that the patient understood the information offered.~~

~~(c) Signature by the patient on a form provided by the department, or one which is substantially similar, acknowledging that she has been provided and has read, or, if unable to read and understand, has had the contents of the document read and explained to her by her prenatal care provider to her satisfaction, complies with the requirements of this section.~~

(b) The person who completes a certificate of live birth must document on the confidential part of each birth certificate:

(1) Whether a standard licensed diagnostic test for HIV was performed on the woman who bore the child.

(2) If a standard licensed diagnostic test for HIV was performed:

(A) The date the blood specimen was taken; and

(B) Whether the test was performed during pregnancy or at the time of delivery.

(3) If a standard licensed diagnostic test for HIV was not performed, the reason the test was not performed.

(Indiana State Department of Health; 410 IAC 1-6-7; filed Feb 9, 1999, 5:13 p.m.: 22 IR 1971; readopted filed Jul 15, 2005, 8:00 a.m.: 28 IR 3661)

SECTION 7.1. 410 IAC 1-6-7.1 IS ADDED TO READ AS FOLLOWS:

410 IAC 1-6-7.1 Newborn testing in the event of maternal refusal

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 pursuant to 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 1-6-7.1; filed)

RULE 7. 410 IAC 1-7 IS AMENDED TO READ AS FOLLOWS:

Rule 7. HIV Counseling and Testing of Pregnant Patients

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

410 IAC 1-7-7 Provider's responsibilities to pregnant patient who has been tested for HIV

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

Sec. 7. (a) A provider, or ~~his or her~~ **provider's** designee, must do the following:

(1) Deliver the test results for HIV infected and HIV uninfected **pregnant** patients in a direct, straightforward, and confidential manner.

(2) Deliver the results at the earliest possible encounter after testing.

(3) Deliver the results face-to-face for HIV infected **pregnant** patients.

(b) If the test results positive, the treating provider, or ~~his or her~~ **provider's** 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**, including reducing the risk of perinatal transmission significantly.**

(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 **in MMWR 51, RR-18.**

(4) Comply with reporting requirements to the local health officer pursuant to 410 IAC 1-2.3-47 regarding a HIV-infected pregnant woman or perinatally exposed infant.

(Indiana State Department of Health; 410 IAC 1-7-7; filed Jun 25, 2004, 11:05 a.m.: 27 IR 3496; readopted filed Jul 15, 2010, 12:12 p.m.: 20100728-IR-410100261RFA)

SECTION 8. 410 IAC 1-7-8 IS AMENDED TO READ AS FOLLOWS:

410 IAC 1-7-8 Pregnant patient 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~~ **patient** must have a complete application for the HIV medical services program on file with the department.

(b) A pregnant ~~woman~~ **patient** 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~~ **patient** 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~~ the commissioner's 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; filed Jun 25, 2004, 11:05 a.m.: 27 IR 3496; readopted filed Jul 15, 2010, 12:12 p.m.: 20100728-IR-410100261RFA)

SECTION 10. 410 IAC 1-7-10 IS AMENDED TO READ AS FOLLOWS:

410 IAC 1-7-10 Information to the HIV-positive pregnant patient

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

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

(1) An explanation of the nature of AIDS and HIV, which~~:~~

~~(A)~~ is consistent with MMWR 41, 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 ~~highrisk~~ **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 MMWR 50, 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 MMWR 50, RR19, including that breastfeeding by an HIV positive woman carries a risk for transmission of the virus from mother to infant.

(6) Referral information to other human immunodeficiency virus (HIV) prevention testing and psychosocial services, if appropriate.

(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; filed Jun 25, 2004, 11:05 a.m.: 27 IR 3497; readopted filed Jul 15, 2010, 12:12 p.m.: 20100728-IR-410100261RFA)

SECTION 11. 410 IAC 1-7-11 IS REPEALED.

~~**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; filed Jun 25, 2004, 11:05 a.m.: 27 IR 3497; readopted filed Jul 15, 2010, 12:12 p.m.: 20100728-IR-410100261RFA)

SECTION 12. 410 IAC 1-7-12 IS AMENDED TO READ AS FOLLOWS:

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~~ **pregnant patient** as detailed in ~~IC 16-41-6-2~~ **IC 16-41-6-8.**

(b) The provider shall inform the ~~woman~~ **pregnant patient** of her options under IC 16-41-6-7.

(Indiana State Department of Health; 410 IAC1-7-12; filed Jun 25, 2004, 11:05 a.m.: 27 IR 3497; readopted filed Jul 15, 2010, 12:12 p.m.: 20100728-IR-410100261RFA)

SECTION 13. 410 IAC 1-7-13 IS AMENDED TO READ AS FOLLOWS:

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~~ **the provider's** designee.
(Indiana State Department of Health; 410 IAC 1-7-13; filed Jun 25, 2004, 11:05 a.m.: 27 IR 3498; readopted filed Jul 15, 2010, 12:12 p.m.: 20100728-IR-410100261RFA)

SECTION 14. 410 IAC 1-7-14 IS AMENDED TO READ AS FOLLOWS:

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 **pregnant** 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; filed Jun 25, 2004, 11:05 a.m.: 27 IR 3498; readopted filed Jul 15, 2010, 12:12 p.m.: 20100728-IR-410100261RFA)

SECTION 15. 410 IAC 1-7-15 IS AMENDED TO READ AS FOLLOWS:

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 **pregnant** 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; filed Jun 25, 2004, 11:05 a.m.: 27 IR 3498; readopted filed Jul 15, 2010, 12:12 p.m.: 20100728-IR-410100261RFA)

SECTION 16. 410 IAC 1-7-16 IS AMENDED TO READ AS FOLLOWS:

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~~ the provider's designee.
(Indiana State Department of Health; 410 IAC 1-7-16; filed Jun 25, 2004, 11:05 a.m.: 27 IR 3498; readopted filed Jul 15, 2010, 12:12 p.m.: 20100728-IR-410100261RFA)