

BEFORE THE INDIANA STATE DEPARTMENT OF HEALTH

**AN ADMINISTRATIVE RULES HEARING
LSA DOCUMENT #11-458**

HEARING OFFICER REPORT

This matter came before the duly appointed Hearing Officer, Allyson Emley, on the 26th day of January, 2012, at 10:00 a.m., at the Indiana State Department of Health (ISDH), 2 North Meridian Street, Indianapolis, Indiana.

Notice of time and place of the hearing was given as provided by law by publishing on November 30, 2011, in the *Indianapolis Star* and by publishing in the *Indiana Register*. Proof of publication of this notice has been received by the ISDH and the notice and proof are hereby incorporated into the record of this cause by reference and placed in the official files of the ISDH.

ORAL STATEMENT

Dr. Elaine Cox

I.U. Health and the Ryan White Center for Pediatric Infectious Disease at Riley Hospital

Ms. Cox testified at the hearing. Her comments are on pages four and five of the public hearing transcript which is attached and incorporated by reference as Exhibit 1.

WRITTEN STATEMENT

No written statements were presented at the hearing.

Comment 1

One comment was submitted to the hearing officer on August 25, 2011 from Dr. Danielle A. Osterholzer, Assistant Professor of Clinical Medicine and Pediatrics, Indiana University School of Medicine and Medical Director, Ryan White HIV Clinic, Wishard Hospital.

Ms. Osterholzer's comment was in reference to the proposed 410 IAC 1-6-7(a)(1). She asked whether, by law, the prenatal care provider must document in the chart that counseling was

BEFORE THE STATE DEPARTMENT OF HEALTH
FOR THE STATE OF INDIANA

IN THE MATTER OF THE PUBLIC
HEARING ON THE HIV RULE

TRANSCRIPT OF PROCEEDINGS
HELD JANUARY 26, 2012
BEFORE HEARING OFFICER ALLYSON EMLEY

EMLEY:

LSA Document Number 11-458 amends 410 I. A. C. 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 rabbit 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 providers' responsibilities to a pregnant patient, and to update references to the Indiana Code. It also adds 410 I. A. C. 1-6-7.1, newborn testing in the event of maternal refusal and repeals 410 I. A. C. 1-7-11, notification to the pregnant woman. This is a public hearing for the Indiana State Department of Health on the 26th day of January, 2012 at 10:00 o'clock A.M. at the Indiana State Department of Health, Third Floor Board Room, Two North Meridian Street, Indianapolis, Indiana and is docketed before the Executive Board of the Indiana State Department of Health as Preliminary Adoption of Amendments to 410 I. A. C. 1, LSA Document Number 11-458. Notice of time and place of this hearing was

given as provided by law by publishing on November 30th, 2011 in The Indianapolis Star and in Indiana Register. Proof of publication of this Notice has been received by the Department and the Notice and Proof are now incorporated in the record of this cause by reference and placed in the official files at the Department. My name is Allyson Emley and I have been appointed Hearing Officer by the Indiana State Department of Health to serve in this cause. The sign-in sheet should be completed by all individuals desiring to be shown as appearing of record and shall be completed by those who desire to be heard in this hearing. If you have not already signed the sheet, please do so at this time. You will also find at the back of the room a copy of the Proposed Rule, a Small Business Economic Impact Statement and the Indiana Economic Development Corporation's comments on the Economic Impact Statement. You are welcome to take a copy of each. Additionally, the Proposed Rule and I. E. D. C. comments are posted on the Department's website at www.in.gov/isdh under Rules. Oral statements will be heard and written statements may be

handed to me, e-mailed to me at aemley@isdh.in.gov or mailed to me at Two North Meridian Street, Section 3H-99, Indianapolis, Indiana, 46204 by close of business today, January 26th, 2012. All written and verbal comments will be recorded in my report on this hearing to the Executive Board of the Indiana State Department of Health. Each person who speaks for the record is required to clearly identify yourself giving your name, spelling it and identifying who you represent. Is there anyone who cares to be heard?

COX:

That would be.

EMLEY:

Okay.

COX:

Dr. Elaine Cox, C-O-X, from I. U. Health and the Ryan White Center for Pediatric Infectious Disease at Riley Hospital. We are extremely grateful for this Rule. There has been one (1) comment by another provider on Section 7, on page three (3), regarding the documentation and although this Rule significantly decreases the documentation that is required, which is important, because that's a barrier to testing, the fact that we have to document in the medical records that the pre-natal care provider

provided the (indiscernible) to the pregnant patient and the concern is that with humanodeficiency virus information and counseling. It isn't that in the course of the discussion with the patient that I don't think that that should occur, I think it needs to be very clear however that no written consent or written attestation by the patient that that occurred is important and I don't know if the person who had the comment to us was concerned that their specific Legal Department, by saying that you have to document that would require that there was a separate sheet that goes in the medical record that would require, that would be required to suffice that part of the Rule. And that's, I think that just completely obliterates the whole intention of opt out, so it would also be better if it could say "provided the following to the pregnant patient". Something like "Notification and Right of Refusal" and some comment to the effect that that doesn't need to be a separate written document, but that was the only comment that we had.

EMLEY: Is there anyone else who would like to be heard? Any other comments? Okay. I want to thank

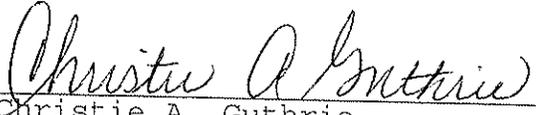
everyone for coming. My report of the hearing will be in writing to the Executive Board of the Indiana State Department of Health for their consideration before final adoption. These proceedings, pursuant to Notice, are hereby concluded. This cause is therefore adjourned until Final Order of the Executive Board. Thank you for coming.

STATE OF INDIANA)
) SS:
COUNTY OF LAWRENCE)

I, Christie A. Guthrie, a Notary Public in and for the County of Lawrence, State of Indiana, do hereby certify that the above and foregoing is a true and accurate transcript of the Rule Hearing regarding the HIV Rule Amendment held before Allyson Emley, Hearing Officer for the Indiana State Department of Health, that the foregoing hearing was held in the offices of the Indiana State Department of Health, Two North Meridian Street, Indianapolis, Marion County, Indiana, on the 26th day of January, 2012; that said hearing was taken down by means of recording and afterwards reduced to typewriting by me.

I do further certify that I am a disinterested person in this cause of action; that I am not a relative or attorney of either party, or otherwise interested in the event of this action, and am not in the employ of the attorneys for the respective parties.

IN WITNESS WHEREOF, I have hereunto set my hand and seal this 2nd day of February, 2012.


Christie A. Guthrie
Notary Public
A Resident of Lawrence Co., IN

My Commission Expires:
December 17, 2017

TITLE 410 INDIANA STATE DEPARTMENT OF HEALTH

Proposed Rule
LSA Document #11-

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 move newborn testing in the event of maternal refusal; to clarify provider's responsibilities to a pregnant patient; and to update references to the Indiana Code. 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 1-7-7; 410 IAC 1-6-4; 410 IAC 1-6-5; 410 IAC 1-7-7; 410 IAC 1-7-11; 410 IAC 1-7-12;

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

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 16-41-6-2.5

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 16-41-6-2.5

Sec. 5. The prenatal care provider primarily responsible for providing prenatal care to a pregnant patient shall ~~offer to obtain an *in-situ* 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 16-41-6-2.5

Sec. 6. (a) In ~~offering providing an *in-situ* 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 woman 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 16-41-6-2.5

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 ~~isic, 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)

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

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

Comment [DO1]: By law, do they have to document in the chart that counseling was given?? I worry that saying this will again lead practices making women sign a piece of paper to say they received counseling about HIV which again is a barrier.

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)

410 IAC 1-7-10 Information to the pregnant-woman-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 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-410100261 RFA)

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-410100261 RFA)~~

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

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