

EXHIBIT F

DEPARTMENT OF HEALTH, STI/HIV/HEPATITIS C/TB SECTION

SUBJECT: Reportable Disease Section XXI, Sexually Transmitted Diseases

DESCRIPTION: These rules are revised to clarify the Communicable Diseases Rules and Regulations Section XXI Sexually Transmitted Disease (Syphilis, Gonorrhea, Chancroid, Lymphogranuloma Venereum, Granuloma Inguinale) and Ophthalmia Neonatorum (Gonorrheal Ophthalmia). This regards Syphilis testing requirements during pregnancy to meet Centers for Disease Control and Prevention (CDC) Guidelines for communities and populations in which the prevalence of syphilis is high and for patients at high risk. Arkansas is ranked in the top five states for congenital syphilis.

A new statement is added to reinforce the importance of HIV testing of pregnant women who are at increased risk of HIV or were not tested for HIV early in their pregnancy.

This change is necessary to protect women and their babies from the serious consequences of untreated syphilis or HIV during pregnancy.

Proposed Change

The proposed change will require that a second serologic test for Syphilis be performed on women during the third trimester, ideally at 28 to 32 weeks gestation and test pregnant women who are at increased risk for HIV Or were not tested for HIV earlier in their pregnancy during the third trimester of their pregnancy.

PUBLIC COMMENT: A public hearing was held September 10, 2014. The public comment period expired September 10, 2014. The Department received no public comments.

Isaac Linam, an attorney with the Bureau of Legislative Research, asked the following question:

QUESTION: Are the CDC guidelines that precipitate this rule change found in the Morbidity and Mortality Weekly Report, December 17, 2010, Vol. 59, No. RR-12? If not, could you send me the appropriate guidelines?

RESPONSE: Yes they are in there.

The proposed effective date for the rule is December 1, 2014.

CONTROVERSY: This is not expected to be controversial.

FINANCIAL IMPACT: The cost is \$7 per syphilis test and it is covered by insurance, including Medicaid.

LEGAL AUTHORIZATION: Ark. Code Ann. § 20-7-109 provides that the Department of Health promulgate reasonable rules to protect public health and safety and to suppress and prevent infectious, contagious, and communicable diseases.

The latest Centers for Disease Control guidelines relating to syphilis testing during pregnancy are found in the CDC's Morbidity and Mortality Weekly Report, December 17, 2010, Vol. 59, No. RR-12, pg. 35. The guidelines state that in areas with a high prevalence of syphilis and for high risk patients, a second serologic testing of syphilis should be performed early in the third trimester. The guidelines also state that pregnant women at high risk for HIV and were not tested before the third trimester should receive an HIV test during the third trimester.

Will this emergency rule be promulgated under the permanent provisions of the Administrative Procedure Act? Yes No

5. Is this a new rule? Yes No
If yes, please provide a brief summary explaining the regulation. _____

Does this repeal an existing rule? Yes No
If yes, a copy of the repealed rule is to be included with your completed questionnaire. If it is being replaced with a new rule, please provide a summary of the rule giving an explanation of what the rule does. _____

Is this an amendment to an existing rule? Yes No
If yes, please attach a mark-up showing the changes in the existing rule and a summary of the substantive changes. **Note: The summary should explain what the amendment does, and the mark-up copy should be clearly labeled "mark-up."**

6. Cite the state law that grants the authority for this proposed rule? If codified, please give the Arkansas Code citation. Ark. Code Ann. § 20-7-101 et seq.

7. What is the purpose of this proposed rule? Why is it necessary? These rules are being revised to update the Reportable Disease Rules and Regulations Section XXI. Sexually Transmitted Disease and Ophthalmia Neonatorum regarding Syphilis and HIV testing requirements during pregnancy to meet Centers for Disease Control and Prevention (CDC) Guidelines for communities and populations in which the prevalence of Syphilis is high and for patients at high risk. Arkansas is ranked in the top five states for congenital syphilis. This change is necessary to protect women and their babies from the serious consequences of syphilis if not treated.

8. Please provide the address where this rule is publicly accessible in electronic form via the Internet as required by Arkansas Code § 25-19-108(b).
<http://www.healthy.arkansas.gov/aboutADH/Pages/RulesRegulationsProposed.aspx>

9. Will a public hearing be held on this proposed rule? Yes No
If yes, please complete the following:

Date: ??????????
Time: 10:00 a.m.
Place: 4815 West Markham Street, Room
??????????

10. When does the public comment period expire for permanent promulgation? (Must provide a date.)

11. What is the proposed effective date of this proposed rule? (Must provide a date.)

FINANCIAL IMPACT STATEMENT

PLEASE ANSWER ALL QUESTIONS COMPLETELY

DEPARTMENT Arkansas Department of Health
DIVISION STI/HIV/Hepatitis C/TB Section
PERSON COMPLETING THIS STATEMENT Dr. Naveen Patil
TELEPHONE NO. (501) 661-2152 **FAX NO.** (501) 661-2226 **EMAIL:** Naveen.Patil@arkansas.gov

To comply with Ark. Code Ann. § 25-15-204(e), please complete the following Financial Impact Statement and file two copies with the questionnaire and proposed rules.

SHORT TITLE OF THIS RULE Rules and Regulations Pertaining to Reportable Disease Section XXI. Sexually Transmitted Disease and Ophthalmia Neonatorum

1. Does this proposed, amended, or repealed rule have a financial impact? Yes No
2. Is the rule based on the best reasonably obtainable scientific, technical, economic, or other evidence and information available concerning the need for, consequences of, and alternatives to the rule? Yes No
3. In consideration of the alternatives to this rule, was this rule determined by the agency to be the least costly rule considered? Yes No

If an agency is proposing a more costly rule, please state the following:

(a) How the additional benefits of the more costly rule justify its additional cost;

(b) The reason for adoption of the more costly rule;

(c) Whether the more costly rule is based on the interests of public health, safety, or welfare, and if so, please explain; and;

(d) Whether the reason is within the scope of the agency's statutory authority; and if so, please explain.

4. If the purpose of this rule is to implement a federal rule or regulation, please state the following:

(a) What is the cost to implement the federal rule or regulation?

Current Fiscal Year

General Revenue _____
Federal Funds _____
Cash Funds _____
Special Revenue _____

Next Fiscal Year

General Revenue _____
Federal Funds _____
Cash Funds _____
Special Revenue _____

Other (Identify) _____

Other (Identify) _____

Total _____

Total _____

(b) What is the additional cost of the state rule?

Current Fiscal Year

Next Fiscal Year

General Revenue _____

General Revenue _____

Federal Funds _____

Federal Funds _____

Cash Funds _____

Cash Funds _____

Special Revenue _____

Special Revenue _____

Other (Identify) _____

Other (Identify) _____

Total _____

Total _____

5. What is the total estimated cost by fiscal year to any private individual, entity and business subject to the proposed, amended, or repealed rule? Identify the entity(ies) subject to the proposed rule and explain how they are affected.

Current Fiscal Year

Next Fiscal Year

\$ _____

\$ _____

The cost is \$7 per syphilis test and is covered by insurance, including Medicaid.

6. What is the total estimated cost by fiscal year to state, county, and municipal government to implement this rule? Is this the cost of the program or grant? Please explain how the government is affected.

Current Fiscal Year

Next Fiscal Year

\$ _____

\$ _____

7. With respect to the agency's answers to Questions #5 and #6 above, is there a new or increased cost or obligation of at least one hundred thousand dollars (\$100,000) per year to a private individual, private entity, private business, state government, county government, municipal government, or to two (2) or more of those entities combined?

Yes No

If YES, the agency is required by Ark. Code Ann. § 25-15-204(e)(4) to file written findings at the time of filing the financial impact statement. The written findings shall be filed simultaneously with the financial impact statement and shall include, without limitation, the following:

- (1) a statement of the rule's basis and purpose;
- (2) the problem the agency seeks to address with the proposed rule, including a statement of whether a rule is required by statute;
- (3) a description of the factual evidence that:
 - (a) justifies the agency's need for the proposed rule; and

- (b) describes how the benefits of the rule meet the relevant statutory objectives and justify the rule's costs;
- (4) a list of less costly alternatives to the proposed rule and the reasons why the alternatives do not adequately address the problem to be solved by the proposed rule;
- (5) a list of alternatives to the proposed rule that were suggested as a result of public comment and the reasons why the alternatives do not adequately address the problem to be solved by the proposed rule;
- (6) a statement of whether existing rules have created or contributed to the problem the agency seeks to address with the proposed rule and, if existing rules have created or contributed to the problem, an explanation of why amendment or repeal of the rule creating or contributing to the problem is not a sufficient response; and
- (7) an agency plan for review of the rule no less than every ten (10) years to determine whether, based upon the evidence, there remains a need for the rule including, without limitation, whether:
 - (a) the rule is achieving the statutory objectives;
 - (b) the benefits of the rule continue to justify its costs; and
 - (c) the rule can be amended or repealed to reduce costs while continuing to achieve the statutory objectives.