EXHIBIT N

DEPARTMENT OF HEALTH, PUBLIC HEALTH LABORATORY

SUBJECT: Testing of Newborn Infants

DESCRIPTION: Act 428 of 2013 does the following:

1. Amends Arkansas Code § 20-15-302 (a) and (b) concerning testing of newborns to broaden the range of disorders that may be added to the newborn bloodspot screening panel. The previous law allowed for testing for a specific set of disorders and other "genetic disorders of metabolism." Act 428 of 2013 deletes the word "metabolism" so that non-metabolic genetic disorders can be added. One such example is severe combined immunodeficiency disorder (SCID), a disorder of the immune system, not metabolism, and considered to have a genetic etiology. The rules will be changed to add SCID to the panel of screening disorders.

2. Prevents a disorder-by-disorder change to the law and allows the Board of Health to add conditions as recommended by the Discretionary Advisory Committee on Heritable Disorders in Newborns and Children (when feasible). This committee advises the Secretary of U.S. Department of Health and Human Services on the most appropriate application of universal newborn screening tests, technologies, policies, guidelines and standards.

The rules also address delays in Newborn Screening Deliver to the Public Health Laboratories. Timely sample delivery has been a persistent problem for most birthing facilities and has led to some extremely serious delays in identifying disorders. To improve sample delivery times, the rules and regulations need to be more specific and in line with national standards.

Therefore, the program wants to change the wording from "Specimens shall be submitted to the Arkansas Department of Health Public Laboratories, Little Rock, Arkansas, within 48 hours of collection," to "Specimens shall be dispatched to the Arkansas Department of Health Public Health Laboratories, Little Rock, Arkansas within one business day of collection."

PUBLIC COMMENT: A public hearing was held on this rule on November 5, 2014. The public comment period expired November 5, 2014. The Department received no public comments.

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

QUESTION #1: What is the Department's "specific statutory authority" for charging the fee under Section IV. Responsibility, B. Payment? See Ark. Code Ann. § 25-15-105.
RESPONSE #1: Pursuant to Ark. Code Ann. § 20-15-304(3)(B), we are to promulgate regulations that establish "the amount to be charged by the central laboratory for processing the specimans." The fee referred to is the fee charged to hospitals for screening the sample.

QUESTION #2: Why is the fee amount not included in this draft of the rule? Has the fee amount been promulgated as a rule? If yes, where? If no, why not?
RESPONSE #2: The fee is negotiated with the Insurance Commission pursuant to 20-15-304(3), which requires us to promulgate regulations in conjunction with the Insurance Commissioner. We have recently discovered that the fee has not been promulgated by either agency. Therefore, we are going to add the fee to our Rule changes. We believe this is a non-substantive change as we gave notice of the new fee with our notice of rulemaking and financial impact statement. **[The fee is set at $121 for the processing and testing of newborn screening specimens.]**

QUESTION #3: Can you send to me or point me to the recommendations made by the Discretionary Advisory Committee on Heritable Disorders in Newborns and Children, which precipitated the promulgation of this rule?
RESPONSE #3: The Department sent the recommendations as requested.

The proposed effective date for the final rule is March 1, 2015.

CONTROVERSY: This is not expected to be controversial.

FINANCIAL IMPACT: In the next fiscal year, the addition cost of the state rule is $1,259,554.25. This would be the newborn screening fee charged to the hospital pursuant to A.C.A. § 20-15-304(3)(B). All entities that submit a sample for newborn screening, with the exception of the Local Health Units, will be charged an increased fee per sample for newborn screening. The estimated cost to the entities is $3,540,636.75 for the current fiscal year and $4,800,191.00 for the next fiscal year.

The department submitted the following Written Findings for the Financial Impact Statement for the Rules and Regulations Pertaining to Testing of Newborn Infants:

1) A statement of the proposed rule or rule change's purpose
To broaden the range of disorders that may be added to the newborn bloodspot screening panel and to specify sample delivery time requirements.

2) The problem the agency seeks to address with the proposed rule, including a statement of whether a rule is required by statute
The agency currently does not meet the scope of testing as recommended by the Discretionary Advisory Committee on Heritable Disorders in Newborns and Children. Arkansas Code § 20-15-302 (a) and (b) states all newborns shall be tested for genetic disorders of metabolism. Act 428 of 2013 deletes the word "metabolism" so that non-metabolic genetic disorders can be added as feasible.

3) A description of the factual evidence that justifies –

a) the agency's need for the proposed rule

The proposed rule is needed for compliance with national recommendations on the recommended uniform screening panel and in timely sample delivery to the lab.

b) describes how the benefits of the rule meet the relevant statutory objectives and justify the rule's costs
Increasing the number of tests to the panel allows for early detection of genetic disorders, such as SCID, and timely medical intervention and treatment. Newborns affected with SCID can be successfully treated if identified and treated within the first 3 months of life. Rapid sample delivery to the lab allows for rapid identification of affected newborns.

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
The only less costly alternative to the proposed rule is to not move forward with the amended rules and regulations. This alternative would not solve the problem of the laboratory's non-compliance of not testing for all disorders as recommended on the recommended uniform screening panel. This alternative would also be detrimental to the health and well-being of the infants screened because the sample delivery time requirements would not be specified as needed for rapid receipt of samples and timely delivery to the lab for testing.

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
None.

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 exiting rules have created or contributed to the problem, an explanation of why amendment or repeat of the rule creating or contributing to the problem is not a sufficient response
The existing rules as they are currently written contribute to the laboratory's non-compliance with the recommended uniform screening panel as described by the Secretary of the U.S Department of Health and Human Services.

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 the costs
c) the rule can be amended or repealed to reduce costs while continuing to achieve the statutory objectives
The laboratory will review the rules and regulations in 2025 and re-evaluate the ability to achieve the statutory objectives and re-affirm the benefits of this rule .

LEGAL AUTHORIZATION: This rule implements Acts 2013, No. 428. Act 428 amended Ark. Code Ann. § 20-15-302 to provide that newborn infants must be tested for

any genetic disorders, not just those of metabolism, mandated by the Department of Health. Act 428 also amended Ark. Code Ann. § 23-79-129, which requires health insurance policies to include coverage for testing of newborn infants for genetic disorders that are not just those of metabolism if those tests are required by law.

Ark. Code Ann. § 20-15-304(3)(B) provides that the Department shall promulgate rules that establish the "amount to be charged by the central laboratory for processing the specimens".

QUESTIONNAIRE FOR FILING PROPOSED RULES AND REGULATIONS WITH THE ARKANSAS LEGISLATIVE COUNCIL AND JOINT INTERIM COMMITTEE

DEPARTMENT/AGENCY Arkansas Department of Health

DIVISION Public Health Laboratory

DIVISION DIRECTOR Glen Baker, MD

CONTACT PERSON Leslie Himstedt

ADDRESS 201 South Monroe Street, Little Rock, Arkansas 72205

PHONE NO. 501-661-2445 **FAX NO.** 501-280-4087 **E-MAIL** Leslie.Himstedt@arkansas.gov

NAME OF PRESENTER AT COMMITTEE MEETING Robert Brech

PRESENTER E-MAIL Robert.Brech@arkansas.gov

INSTRUCTIONS

A. Please make copies of this form for future use.
B. Please answer each question completely using layman terms. You may use additional sheets, if necessary.
C. If you have a method of indexing your rules, please give the proposed citation after "Short Title of this Rule" below.
D. Submit two (2) copies of this questionnaire and financial impact statement attached to the front of two (2) copies of the proposed rule and required documents. Mail or deliver to:

Donna K. Davis
Administrative Rules Review Section
Arkansas Legislative Council
Bureau of Legislative Research
One Capitol Mall, 5th Floor
Little Rock, AR 72201

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1. What is the short title of this rule? Rules and Regulations Pertaining to Testing of Newborn Infants

2. What is the subject of the proposed rule? expansion of testing menu to include non-metabolic disorders and to specify sample delivery time requirements

3. Is this rule required to comply with a federal statute, rule, or regulation? Yes ☐ No ☒
   If yes, please provide the federal rule, regulation, and/or statute citation.

4. Was this rule filed under the emergency provisions of the Administrative Procedure Act? Yes ☐ No ☒
   If yes, what is the effective date of the emergency rule?

   When does the emergency rule expire?

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. Arkansas Code 20-15-302 (a) and (b)

7. What is the purpose of this proposed rule? Why is it necessary? To allow the NBS program to add new tests as they are available based on national recommendations for screening and to specify sample delivery time requirements in order to more rapidly identify babies with disorders

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). www.healthy.arkansas.gov/programservices/familyhealth/childandadolescenthealth/newbornscreening/healthprofessionals/pages/default.aspx

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

Date: November 5, 2014
Time: 1:00 p.m.
Place: Public Health Laboratory, 1st floor training room

10. When does the public comment period expire for permanent promulgation? (Must provide a date.)
November 5, 2014

11. What is the proposed effective date of this proposed rule? (Must provide a date.)
March 1, 2015

12. Do you expect this rule to be controversial? Yes ☐ No ☒
If yes, please explain. _____

13. Please give the names of persons, groups, or organizations that you expect to comment on these rules? Please provide their position (for or against) if known.

AR Chapter March of Dimes, birth facilities in the state and Arkansas Children's Hospital, midwives and the AR Chapter of the American Academy of Pediatrics

FINANCIAL IMPACT STATEMENT

PLEASE ANSWER ALL QUESTIONS COMPLETELY

DEPARTMENT Arkansas Department of Health
DIVISION Public Health Laboratory
PERSON COMPLETING THIS STATEMENT Leslie Himstedt
TELEPHONE NO. 501-661-2445 **FAX NO.** 501-280-4087 **EMAIL:** Leslie.Himstedt@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 Testing of Newborn Infants

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		**Next Fiscal Year**	
General Revenue	0	General Revenue	0
Federal Funds	0	Federal Funds	0
Cash Funds	0	Cash Funds	0
Special Revenue	0	Special Revenue	0
Other (Identify)	0	Other (Identify)	0

Total	0	Total	0

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

Current Fiscal Year		Next Fiscal Year	
General Revenue	0	General Revenue	0
Federal Funds	0	Federal Funds	0
Cash Funds	0	Cash Funds	0
Special Revenue	0	Special Revenue	0
Other (Identify)	0	Other (Identify)	1,259,554.25
Total	0	Total	1,259,554.25

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
$ 3,540,636.75

Next Fiscal Year
$ 4,800,191.00

all entities that submit a sample for newborn screening, with the exception of the Local Health Units, will be charge an increased fee per sample for newborn screeening.

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
$ n/a

Next Fiscal Year
$ n/a

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.

Written Findings for the Financial Impact Statement
for the Rules and Regulations Pertaining to Testing of Newborn Infants

1) A statement of the proposed rule or rule change's purpose

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Increasing the number of tests to the panel allows for early detection of genetic disorders, such as SCID, and timely medical intervention and treatment. Newborns affected with SCID can be successfully treated if identified and treated within the first 3 months of life.

Rapid sample delivery to the lab allows for rapid identification of affected newborns.

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The laboratory will review the rules and regulations in 2025 and re-evaluate the ability to achieve the statutory objectives and re-affirm thebenefits of this rule .