

**QUESTIONNAIRE FOR FILING PROPOSED RULES WITH THE
ARKANSAS LEGISLATIVE COUNCIL**

DEPARTMENT/AGENCY Department of Health
DIVISION Public Health Lab
DIVISION DIRECTOR Dr. Glen Baker
CONTACT PERSON Laura Shue, General Counsel
ADDRESS 4815 West Markham
PHONE NO. 501-661-2297 FAX NO. _____ E-MAIL Laura.shue@arkansas.gov
NAME OF PRESENTER AT COMMITTEE MEETING Dr. Glen Baker, Laura Shue
PRESENTER E-MAIL laura.shue@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:

Jessica C. Sutton
Administrative Rules Review Section
Arkansas Legislative Council
Bureau of Legislative Research
One Capitol Mall, 5th Floor
Little Rock, AR 72201

- 1. What is the short title of this rule? Rules pertaining to Testing of Newborn Infants
- 2. What is the subject of the proposed rule? Newborn Testing
- 3. Is this rule required to comply with a federal statute, rule, or regulation? Yes _____ No X
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 X
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 X If yes, please provide a brief summary explaining the rule.

Does this repeal an existing rule? Yes _____ No X If yes, a copy of the repealed rule is to be included with your completed questionnaire.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 X 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. Act 58 of 2019, § 20-15-301, and 304

7. What is the purpose of this proposed rule? Why is it necessary?

The proposed amendments add testing for Spinal Muscular Atrophy (SMA) pursuant to Act 58 of 2019. A health benefit plan that is offered, issued, or renewed must provide coverage for newborn screening for spinal muscular atrophy by a healthcare professional on or after January 1, 2020. The rule amendments also add testing for Pompe disease, Mucopolysaccharidosis (MPS1), and Adrenoleukodystrophy (X-ALD). Pursuant to state law, the Board of Health is authorized to set a reasonable fee, which will increase by \$10.00 to cover all four new tests.

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.healtharkansas.gov

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

Date: February 12, 2020

Time: 1:00 pm

Place: 1st Floor Conference Room, Public Health Laboratory, 201 South Monroe Street, Little Rock

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

February 12, 2020

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

upon Legislative approval

12. Please provide a copy of the notice required under Ark. Code Ann. § 25-15-204(a), and proof of the publication of said notice. Attached

13. Please provide proof of filing the rule with the Secretary of State as required pursuant to Ark. Code Ann. § 25-15-204(e). Attached

14. 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.

FINANCIAL IMPACT STATEMENT

PLEASE ANSWER ALL QUESTIONS COMPLETELY

DEPARTMENT Department of Health
DIVISION Public Health Lab
PERSON COMPLETING THIS STATEMENT Laura Shue, General Counsel
TELEPHONE NO. 501-661-2297 FAX NO. _____ EMAIL: laura.shue@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 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, in order to comply with Act 58 of 2019 in the most cost-effective manner. Disorders need to be detected soon after birth for treatment to be most effective.

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;

The additional \$10 fee provides for the extra cost of equipment, test validation, staff training, cost to process, and test the specimens.

- (b) The reason for adoption of the more costly rule;
Compliance with Act 58 of 2019 and addition of three additional tests.

- (c) Whether the more costly rule is based on the interests of public health, safety, or welfare, and if so, please explain; and
The Board of Health and the Public Health Lab determined that the additional tests, for Spinal Muscular Atrophy, Pompe disease, Mucopolysaccharidosis (MPS1), and Adrenoleukodystrophy (X-ALD) will increase screening for the disorders, which can assist health professionals in providing treatment during the critical early months of life when it could be most effective.

- (d) Whether the reason is within the scope of the agency's statutory authority, and if so, please explain. State law authorizes the Board of Health to add additional tests for disorders if reliable and efficient testing techniques are available. See Ark. Code Ann. § 20-15-302. State law requires reimbursement for the cost of the tests. See Ark. Code Ann. § 20-15-302. The Department of Health prescribes the tests that may be administered, and what persons and institutions shall be required to obtain specimens from newborn infants, and the amount to be charged by the central laboratory for processing the specimens. See Ark. Code Ann. § 20-15-304.

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 _____
 Federal Funds _____
 Cash Funds _____
 Special Revenue _____
 Other (Identify) _____
 Total _____

General Revenue _____
 Federal Funds _____
 Cash Funds _____
 Special Revenue _____
 Other (Identify) _____
 Total _____

(b) What is the additional cost of the state rule? (per DHS, Division of Medical Services)

Current Fiscal Year

Next Fiscal Year

General Revenue _____ \$32,421 _____
 Federal Funds _____ \$80,114 _____
 Cash Funds _____
 Special Revenue _____
 Other (Identify) _____
 Total _____ \$112,535 _____

General Revenue _____ \$63,987 _____
 Federal Funds _____ \$161,083 _____
 Cash Funds _____
 Special Revenue _____
 Other (Identify) _____
 Total _____ \$225,070 _____

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

\$ _____

\$ _____

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

\$ _____ \$32,421 _____

\$ _____ \$63,987 _____

_____ (Implementation costs per DHS, Division of Medical Services) _____

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 X No

Act 58 of 2019 requires insurers to cover testing for SMA. Currently, testing costs \$121 per sample. Testing fees would increase what ADH Public Health Lab charges hospitals by \$10 for all four tests.

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; to comply with Act 58 of 2019, and detect disorders early for treatment.
- (2) the problem the agency seeks to address with the proposed rule, including a statement of whether a rule is required by statute; Rule required by statute. Disorders need to be detected soon after birth for treatment to be most effective.
- (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; Early detection for the four conditions decreases medical costs as early treatment is more cost effective.
- (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; There are no alternatives.
- (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; There are no proposed alternatives.
- (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 Previous newborn screenings did not include these tests.
- (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.

ADH constantly monitors CDC guidelines, state and federal laws and regulations for opportunities to reduce and control costs.



Arkansas Department of Health

4815 West Markham Street • Little Rock, Arkansas 72205-3867 • Telephone (501) 661-2000

Governor Asa Hutchinson

Nathaniel Smith, MD, MPH, Secretary of Health

Rules pertaining to Testing of Newborn Infants

The proposed amendments to the Rules pertaining to Testing for Newborn Infants adds tests for newborn screening including for Spinal Muscular Atrophy, (SMA), pursuant to Act 58 of 2019. The proposed amendments to the Rules also add three additional tests for Pompe Disease, MPS 1 spectrum of disease, and childhood onset (cerebral) X-ALD.

At the present time, 31 tests are performed on newborns, and 29 of the tests are performed in the Public Health Laboratory. The tests are performed on dried blood spots that are collected from the infants soon after 24 hours of birth. Of the four additional tests, three of them have FDA-approved procedures, while Spinal Muscular Atrophy does not at this time. The four tests can be performed in our local health laboratory utilizing existing blood samples without having to require new blood samples from the hospital.

The current fee is \$121.00 and the proposed amendment adds an additional \$10.00 charge for the SMA test.

Stricken language would be deleted from and underlined language would be added to present law.
Act 58 of the Regular Session

1 State of Arkansas
2 92nd General Assembly
3 Regular Session, 2019
4

As Engrossed: H1/23/19

A Bill

HOUSE BILL 1074

5 By: Representative J. Mayberry
6 By: Senator Hester
7

For An Act To Be Entitled

9 AN ACT TO REQUIRE NEWBORN SCREENING FOR SPINAL
10 MUSCULAR ATROPHY; TO MANDATE THAT INSURANCE POLICIES
11 COVER NEWBORN SCREENING FOR SPINAL MUSCULAR ATROPHY;
12 AND FOR OTHER PURPOSES.
13
14

Subtitle

15 TO REQUIRE NEWBORN SCREENING FOR SPINAL
16 MUSCULAR ATROPHY; AND TO MANDATE THAT
17 INSURANCE POLICIES COVER NEWBORN
18 SCREENING FOR SPINAL MUSCULAR ATROPHY.
19
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21

22 BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF ARKANSAS:
23

24 *SECTION 1. Arkansas Code § 20-15-302(a)(1)(A), concerning testing of*
25 *newborn infants, is amended to read as follows:*

26 *(a)(1)(A) All newborn infants shall be tested for phenylketonuria,*
27 *hypothyroidism, galactosemia, cystic fibrosis, ~~and~~ sickle-cell anemia, and*
28 *spinal muscular atrophy.*
29

30 *SECTION 2. Arkansas Code Title 23, Chapter 79, is amended to add an*
31 *additional subchapter to read as follows:*

32 *Subchapter 18 – Coverage for Newborn Screening for Spinal Muscular Atrophy*
33

34 *23-79-1801. Definitions.*

35 *As used in this subchapter:*

36 *(1)(A) “Health benefit plan” means:*



1 (i) An individual, blanket, or group plan, policy,
2 or contract for healthcare services issued or delivered by an insurer, health
3 maintenance organization, hospital medical service corporation, or self-
4 insured governmental or church plan in this state; and

5 (ii) Any health benefit program receiving state or
6 federal appropriations from the State of Arkansas, including the Arkansas
7 Medicaid Program, the Health Care Independence Program, commonly referred to
8 as the "Private Option", and the Arkansas Works Program, or any successor
9 program.

10 (B) "Health benefit plan" includes:

11 (i) An indemnity and managed care plan; and

12 (ii) A nonfederal governmental plan as defined in 29
13 U.S.C. § 1002(32), as it existed on January 1, 2019.

14 (C) "Health benefit plan" does not include:

15 (i) A disability income plan;

16 (ii) A credit insurance plan;

17 (iii) Insurance coverage issued as a supplement to
18 liability insurance;

19 (iv) Medical payments under an automobile or
20 homeowner's insurance plan;

21 (v) A health benefit plan provided under Arkansas
22 Constitution, Article 5, § 32, the Workers' Compensation Law, § 11-9-101 et
23 seq., or the Public Employee Workers' Compensation Act, § 21-5-601 et seq.;

24 (vi) A plan that provides only indemnity for
25 hospital confinement;

26 (vii) An accident-only plan;

27 (viii) A specified disease plan; or

28 (ix) A long-term care only plan;

29 (2) "Healthcare professional" means a person who is licensed,
30 certified, or otherwise authorized by the laws of this state to administer
31 health care in the ordinary course of the practice of his or her profession;

32 (3) "Newborn" means a child who is twenty-nine (29) days of age
33 or younger; and

34 (4) "Spinal muscular atrophy" means a genetic disease that
35 affects the part of the nervous system that controls voluntary muscle
36 movement.

1
2 23-79-1802. Coverage for newborn screening for spinal muscular
3 atrophy.

4 (a) A health benefit plan that is offered, issued, or renewed in this
5 state shall provide coverage for newborn screening for spinal muscular
6 atrophy by a healthcare professional on or after January 1, 2020.

7 (b) The coverage for newborn screening for spinal muscular atrophy
8 under this section:

9 (1) Is not subject to policy deductibles or copayment
10 requirements; and

11 (2) Does not diminish or limit benefits otherwise allowable
12 under a health benefit plan.

13
14 */s/J. Mayberry*

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17 **APPROVED: 2/4/19**
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