ARKANSAS REGISTER

Transmittal Sheet

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Secretary of State
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For Office Use Only:

Effective Date _____ Code Number _____

Name of Agency Arkansas Department of Health

Department Public Health Labratories

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Statutory Authority for Promulgating Rules Ark. Code Ann. § 20-15-301 et seq.

Rule Title: Rules Pertaining to Testing of Newborn Infants

Intended Effective Date (Check One)

- ☐ Emergency (ACA 25-15-204)
- ☑ 10 Days After Filing (ACA 25-15-204)
- ☐ Other _____ (Must be more than 10 days after filing date.)

Date	
Legal Notice Published	01/05/20
Final Date for Public Comment	02/12/20
Reviewed by Legislative Council	03/20/20
Adopted by State Agency	10/24/19

Electronic Copy of Rule e-mailed from: (Required under ACA 25-15-218)

Laura Shue	Laura.Shue@arkansas.gov	03/23/20
Contact Person	E-mail Address	Date

CERTIFICATION OF AUTHORIZED OFFICER

I Hereby Certify That The Attached Rules Were Adopted
In Compliance with the Arkansas Administrative Act. (ACA 25-15-201 et. seq.)

Signature

501-661-2297 Laura.Shue@arkansas.gov
Phone Number E-mail Address

General Counsel
Title

03/23/20
Date

Revised 7/2015 to reflect new legislation passed in the 2015 Regular Session (Act 1258). This act changed the effective date from 30 days to 10 days after filing the rule.

ARKANSAS STATE BOARD OF HEALTH

RULES PERTAINING TO
TESTING OF NEWBORN INFANTS

Promulgated Under the Authority of
Ark. Code Ann. § 20-15-301 et
seq., and Act 58 of 2019

Effective on April 1, 2020

Arkansas Department of Health
Nathaniel Smith, MD, MPH,
Secretary of Health

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SECTION I. DEFINITIONS.

A. **Phenylketonuria (PKU)**, **Congenital Hypothyroidism (CH)** and **Galactosemia** are conditions (diseases) which cause irreversible brain damage and mental retardation unless they are detected and treated at a very early stage in the life of a newborn individual. Untreated Galactosemia also results in liver disease, cataracts, and increased susceptibility to serious infection. Early diagnosis and treatment are absolutely essential in order to avoid these health problems.

B. **Sickle Cell Disease (SS)** is the most common inherited abnormality of a red blood cell protein called hemoglobin. It is caused by a genetic abnormality that must be inherited from both parents. Sickle Cell Disease may cause serious health problems even in the first few months of life. It occurs much more commonly in people of African American, Asian and Mediterranean descent. In addition to the anemia, it lowers resistance to infection, and is associated with increased morbidity and mortality unless diagnosed and treated early. Sickle Cell Disease is one of a handful of related hemoglobinopathies each of which can cause similar health problems with varying severity.

C. **Sickle Cell Trait (AS)** and other hemoglobinopathy traits differ from their corresponding diseases. Traits occur when the genetic abnormality is inherited from only one parent, the other parent contributing a normal gene. Hemoglobinopathy traits cause only minor health issues that show up occasionally in life. They are associated with normal life spans. Sickle Cell Trait (AS) is the most common, occurring in 8 to 10% of African Americans.

D. **Biotinidase Deficiency (BIOT)** is caused by the lack of an enzyme called biotinidase, resulting in an inability of the body to use Vitamin B substances absorbed by the intestines. Without sufficient biotin, several other critical enzyme systems are unable to function properly. Biotinidase deficiency can lead to seizures, developmental delay, skin rash, and hearing loss. Newborns with the disorder appear normal, but develop critical symptoms after the first weeks or months of life. Symptoms include floppiness, seizures, developmental delay, hair loss, rashes, hearing loss and vision loss. Metabolic acidosis can result in coma and death. A daily biotin dietary supplement can prevent all symptoms.

E. **Congenital Adrenal Hyperplasia (CAH)** is a group of disorders caused by the deficiency of an adrenal enzyme resulting in decreased production of important hormones called cortisol and aldosterone. Cortisol helps the body respond to stressful events. Aldosterone helps the body maintain its fluids and salts. Without enough of these hormones, the affected newborn may appear normal, but can quickly develop symptoms including lethargy, vomiting, muscle weakness and dehydration. In severe cases death may occur within a few weeks if left untreated. One kind of CAH may show up first as ambiguous genitalia in the newborn. Infants with milder forms of the disorder are still at risk for reproductive and growth difficulties. If detected early and maintained on appropriate doses of medication, infants diagnosed with CAH can have normal growth and development.

F. **Cystic Fibrosis (CF)** is a disorder in which the body cannot make an important protein involved in using chloride ions, an ingredient in table salt. The major clinical consequences are the production of abnormally thickened mucous secretions in the lungs and digestive systems of affected newborns. With early detection and lifelong comprehensive treatment plans, infants diagnosed with CF can be expected to live longer and in a better state of health than in the past.

G. **Amino Acid Disorders** make up a group of inherited conditions in which protein metabolism is disrupted. Onset of symptoms may occur shortly after birth or after an apparently normal neonatal period. The symptoms may occur in episodes with normal periods in between. The clinical onset may include unusual odors in the urine, irritability, poor feeding, changes in muscle tone, lightened pigmentation, failure to thrive, jaundice, or liver enlargement. Other symptoms include intoxication-like symptoms such as vomiting, lethargy, seizures, and coma. Treatment of amino acid metabolism disorders includes a low-protein diet strictly controlling intake of specific amino acids.

H. **Fatty Acid Oxidation Disorders** make up a group of genetic metabolic deficiencies in which the body is unable to oxidize (break down) fatty acids to make energy. An enzyme is either missing or not working correctly. The main source of energy for the body is a sugar called glucose. Normally when the glucose runs out, fat is broken down into energy. However, that energy is not readily available to children and adults with a fatty acid oxidation disorder. If undiagnosed and untreated, these disorders can lead to serious complications affecting the liver, heart, and eyes; general muscle development; and possibly death. Symptoms of a metabolic "crisis" include vomiting, diarrhea, lethargy and difficulty breathing.

I **Organic Acid Disorders** make up a group of inherited metabolic diseases that lead to accumulation of organic acids in biological fluids (e.g., blood and urine). The accumulation produces disturbances in the acidity of the body and causes alterations in metabolic chemical reactions. These disorders can cause intoxication-like symptoms such as vomiting, metabolic acidosis, ketosis, dehydration, or coma. Some patients may have too little sugar in the blood, or too much lactic acid or ammonia. Chronic symptoms include recurrent vomiting, failure to thrive, floppiness and general developmental delay. Symptoms of these disorders can be diminished by restricting protein in the diet and, in some cases, supplementation with vitamins or a nutrient called carnitine.

J. **Severe Combined Immunodeficiency (SCID)** is a group of disorders characterized by severe defects in the T-lymphocyte and B-lymphocyte systems. Affected babies are susceptible to multiple types of life-threatening bacterial, viral, and fungal infections. Early diagnosis of SCID is imperative as SCID is curable with hematopoietic stem cell transplantation. Infants with SCID die of infections by age two (2) years unless immunity is reconstituted by treatment. SCID is commonly known as the "bubble boy" disease.

K. The **Collector** is the person or party responsible for collecting and submitting the blood specimen for testing. The persons or parties who are collectors under these Rules and Regulations are described in Section IV.A.

L. **The Department** is the Arkansas Department of Health.

M. **Spinal muscular atrophy (SMA)** is a genetic disease affecting the central nervous system, peripheral nervous system, and voluntary muscle movement (skeletal muscle). Most of the nerve cells that control muscles are located in the spinal cord, which accounts for the word spinal in the name of the disease.

N. **Pompe disease** is an inherited disorder caused by the buildup of a complex sugar called glycogen in the body's cells. The accumulation of glycogen in certain organs and tissues, especially muscles, impairs their ability to function normally.

O. **Mucopolysaccharidosis** (MPS1) refers to a group of inherited conditions in which the body is unable to properly breakdown mucopolysaccharides (long chains of sugar molecules that are found throughout the body). As a result, these sugars buildup in cells, blood and connective tissue which can lead to a variety of health problems.

P. **Adrenoleukodystrophy** (X-ALD) is a disease linked to the X chromosome. It is a result of

fatty acid buildup caused by the relevant enzymes not functioning properly, which then causes damage to the myelin sheath of the nerves, resulting in seizures and hyperactivity. Other symptoms include problems with speaking, listening, and understanding verbal instructions.

SECTION II. PURPOSE.

The purpose of these Rules is to assure that all infants born in Arkansas have the opportunity to be screened for genetic illnesses.

These Rules provide a method to assure that:

1. All newborn infants are tested for Phenylketonuria (PKU), Congenital Hypothyroidism (CH), Galactosemia, Sickle Cell Disease (SS), Biotinidase Deficiency (BIOT), Congential Adrenal Hyperplasia (CAH), Cystic Fibrosis (CF), Amino Acid Disorders, Fatty Acid Oxidation Disorders, Organic Acid Disorders, ~~and~~ Severe Combined Immunodeficiency (SCID), Spinal Muscular Atrophy (SMA), Pompe Disease, MPS 1 spectrum of disease, and childhood onset (cerebral) X-ALD.

2. All newborns with an abnormal screen receive appropriate medical follow-up.

SECTION III. AUTHORITY.

These Rules are promulgated pursuant to the authority conferred by Arkansas Code Annotated § 20-15-301 et seq. and Act 58 of 2019.

SECTION IV. RESPONSIBILITY.

A. Collection and Submission.

1. Medical Facilities/Medical Staff: In all cases where the birth of an infant occurs in a medical facility licensed by the Board of Health, it shall be the responsibility of the governing body and medical staff of the facility to adopt and enforce policies and procedures which ensures that blood test for Phenylketonuria (PKU), Congenital Hypothyroidism (CH), Galactosemia, Sickle Cell Disease (SS), Biotinidase Deficiency (BIOT), Congenital Adrenal Hyperplasia (CAH), Cystic Fibrosis (CF), Amino Acid Disorders, Fatty Acid Oxidation Disorders, Organic Acid Disorders, ~~and~~ Severe Combined Immunodeficiency (SCID), Spinal Muscular Atrophy (SMA), Pompe Disease, MPS 1 spectrum of disease, and childhood onset (cerebral) X-ALD are conducted and processed in accordance with these rules. The licensed facility shall also be responsible for submission of the usable blood specimen in cases where an infant less than six months of age is admitted (i.e., born out of hospital, neonatal transfer, etc.), and it is brought to the attention of the facility or the attending physician that the infant is untested. If an infant is discharged from a licensed medical facility without collection and submission of a usable specimen for testing, it shall be the responsibility of the

discharging facility and the attending physician to arrange for the testing. The discharging facility and attending physician shall notify the Arkansas Department of Health ("Department") within one week of discharge if their efforts fail to arrange for testing.

2. Physicians: Physicians assuming care of infants who are under six months of age and who come to their attention as being untested or inadequately tested for Phenylketonuria (PKU), Congenital Hypothyroidism (CH), Galactosemia, Sickle Cell Disease (SS), Biotinidase Deficiency (BIOT), Congenital Adrenal Hyperplasia (CAH), Cystic Fibrosis(CF), Amino Acid Disorders, Fatty Acid Oxidation Disorders, Organic Acid Disorders, ~~and~~ Severe Combined Immunodeficiency (SCID), Spinal Muscular Atrophy (SMA), Pompe Disease, MPS 1 spectrum of disease, and childhood onset (cerebral) X-ALD, shall also be responsible for assuring collection and submission of usable blood specimens for these infants.

3. Licensed Midwives: In cases where the birth occurs outside a licensed medical facility or in the home, it shall be the responsibility of an attending licensed midwife to advise the parents of this law and the procedure for conducting newborn screening, and documenting that a blood sample is obtained after 24 hours and no later than 72 hours after birth. If the blood sample is not obtained for any reason, an attending licensed midwife must document the incident in the patient's chart.

4. The Department: The Department's Local Health Unit shall collect and submit usable blood specimens on all infants under six months of age who come to their attention as being tested or inadequately tested. This responsibility shall not be in lieu of that of the preceding individuals and facilities.

B. Payment

1. The Collector will be charged a fee of one hundred and thirty-one dollars ($131.00) for the processing and testing of newborn screening specimens by the Department.

2. The Board of Health may determine the amount of this fee based on the Department's cost to process and test the specimens.

C. Laboratory Analysis

1. The Department shall be responsible for provision of forms and instructions for the blood specimen collection; processing and recording of the specimen received; analysis of specimen; determination of abnormal results; and reporting of lab results within a time period which would allow preventive medical intervention.

D. Follow-Up

1. The Department shall be responsible for the interpretation of laboratory results and the reporting of abnormal results to the attending physician or birth attendant. If the screening result is suggestive of Classical or Variant

PKU, Galactosemia, Sickle Cell Disease (SS), Biotinidase Deficiency (BIOT), Congenital Adrenal Hyperplasia (CAH), Cystic Fibrosis (CF), Amino Acid Disorders, Fatty Acid Oxidation Disorders, Organic Acid Disorders, ~~or~~ Severe Combined Immunodeficiency (SCID), Spinal Muscular Atrophy (SMA), Pompe Disease, MPS 1 spectrum of disease, or childhood onset (cerebral) X-ALD, the Department shall consult with specialist physicians who are retained by contract to provide clinical advice on these conditions. The Department shall notify the Collector of the specimen and enter the infant's information in a tracking system maintained to evaluate program operations and infants' medical outcomes.

2. Attending Physician/Medical Attendant:

a) Upon receipt of a notice of an abnormal test result the physician or medical attendant shall be responsible for the appropriate medical treatment, referral, and/or retesting within the timeframe specified by the Department for that particular disorder. It is strongly recommended that consultation be obtained with a physician who has special competence in the management of these disorders.

b) The attending physician or other responsible health care provider who conducts testing in follow-up to abnormal screens shall report subsequent test results (whether negative or positive) to the Department. To provide for long term follow up the Department will collect data on affected infants each year for five years to determining health care maintenance and health status, especially the presence of mental retardation or permanent disability.

The Department will establish protocols for follow-up of all screened disorders in collaboration with medical specialists under contract. For infants with abnormal test results, the physician will be notified of the results and informed of the recommended protocols for follow-up of the specific order.

SECTION V. SPECIMEN COLLECTION AND SUBMISSION

A. The blood specimen for PKU, CH, Galactosemis, Sickle Cell Anemia, Biotinidase (BIOT), Congenital Adrenal Hyperplasia (CAH), Cystic Fibrosis (CF), Amino Acid Disorders, Fatty Acid Oxidation Disorders, Organic Acid Disorders, ~~or~~ Severe Combined Immunodeficiency (SCID), or Spinal Muscular Atrophy (SMA), Pompe Disease, MPS 1 spectrum of disease, and childhood onset (cerebral) X-ALD testing must be collected and submitted as described below:

B. Timing of Specimen Collection

1. For all healthy infants born in medical facilities, the specimen shall be collected before the time of discharge from the facility. Optimum time for collection is 24 to 72 hours after birth, and all Collectors should strive to comply with that time frame. If any infant is discharged or specimen

collected prior to 24 hours of age, a repeat test shall be arranged by the medical facility and the attending physician. This repeat specimen shall be collected by the infant's seventh day of life. A repeat test for Sickle Cell Disease shall not be required if specimen was collected prior to 24 hours of age.

2. Specimens from ill or premature infants shall be obtained as soon as possible after their condition has sufficiently stabilized.

3. Specimens from infants not born in medical facilities shall be collected between 24 and 72 hours after birth.

Infants under six months of age who are known to be untested or inadequately tested shall have blood specimens collected and submitted by the responsible authority as soon as possible.

C. Specimen Collection and Submission

1. Specimens shall be dispatched to the Arkansas Department of Health Public Health Laboratories, Little Rock, Arkansas, no later than one (1) business day from collection. Specimens are submitted only on forms provided by the Public Health Laboratory. The Collector is responsible for supplying complete and accurate identifying information on the collection form to be used for tracking infants with abnormal screening results.

D. Forms

1. Submission: forms may be obtained by writing to the Public Health Laboratories at:

Arkansas Department of Health
201 South Monroe Street
Little Rock, AR 72205

The county health units will not supply these forms.

E. Unsatisfactory Specimens

1. Inadequate, contaminated, or otherwise unusable specimens shall be reported to the Collector after laboratory determination of an unsatisfactory specimen. The Collector shall be responsible for assuring recollection and resubmission within seven calendar days of notification.

SECTION VI. ANALYSIS, INTERPRETATION, AND REPORTING OF RESULTS

A. Laboratory Analysis

1. All specimens received by the laboratory shall be initially examined within five working days of receipt. Abnormal results shall be reported to the Collector within two working days of determination.

B. Interpretations of Results

1. Phenylketonuria (PKU)

a) The Department shall define the phenylalanine level which constitutes a positive screening result for PKU.

b) An infant whose phenylalanine level is determined by the Department to be negative for PKU requires no action to be taken. However, attending physicans shall give special consideration when testing circumstances or infant evaluation/family history suggests the possibility of need for prescreening in cases where PKU of PKU variants may actually exist in spite of initial negative screening results.

2. Congenital Hypothyroidism (CH)

a) The Department shall define the thyroxine and thyroid stimulating hormone levels which constitute positive screening results for CH.

b) Occasionally test results suggestive of CH may be reported which, upon retesting, will be found within normal limits. Likewise it is possible that test results which are reported as normal in the neonatal period could mask the delayed onset of CH. While an infrequent occurrence, in the face of clinical findings, this possibility must be considered by the attending physician.

3. Galactosemia

a) The Department shall define the galactose-1-phosphate uridyl transferase (GALT) levels which constitute positive screening results for Galactosemia.

b) It is possible that an infant affected with Galatosemia could have normal initial screening results. This situation is most likely to occur in infants who have received no or insufficient feedings with lactose-containing milk or formula prior to testing, or who have received blood transfusions prior to testing.

c) The medical caretaker shall give special consideration to retesting any infant whose case findings, testing circumstances, or family history seems to medically warrant it.

4. Sickle Cell Anemia or Trait

a) The Department shall define the laboratory value which constitutes a positive screening result for Sickle Cell Disease (SS), Sickle Cell Trait (AS) or other related hemoglobinopathy.

b) An infant whose hemoglobin is determined by the Department to be negative for SS or other related serious hemoglobinopathies requires no special consultation; however, infants with trait conditions should be followed for mild anemias and urinary tract infections.

c) The medical caretaker shall give special consideration to re-testing any infant whose case findings, testing circumstances, or family history seems to medically warrant it.

5. Biotinidase Deficiency (BIOT), Congenital Adrenal Hyperplasia

(CAH), Cystic Fibrosis (CF), Amino Acid Disorders, Fatty Acid Oxygenation Disorders, Organic Acid Disorders, Severe Combined Immunodeficiency (SCID).

a) The Department shall define the laboratory value which constitutes a positive screening result for Biotinidase Deficiency (BIOT), Congenital Adrenal Hyperplasia (CAH), Cystic Fibrosis (CF), Amino Acid Disorders, Fatty Acid Oxidation Disorders, Organic Acid Disorders Severe Combined Immunodeficiency (SCID).

C. Reporting of Results

1. Phenylketonuria (PKU), Congenital Hypothyroidisn (CH), Galactosemia Biotinidase Deficiency (BIOT), Congenital Adrenal Hyperplasia (CAH), Cystic Fibrosis (CF), Amino Acid Disorders, Fatty Acid Oxidation Disorders, Organic Acid Disorders Severe Combined Immunodeficiency (SCID).

a) Immediately upon obtaining the initial positive screening result, the Department shall notify the attending physician or medical attendant, who shall be responsible for ensuring that prompt follow-up diagnostic testing is conducted.

b) Appropriate, expectant medical management shall not be withheld pending the confirmatory test results. A non-physician Collector shall immediately refer the infant for appropriate medical intervention. It is recommended that a pediatric geneticist, endocrinologist, or pulmonologist consultant be utilized in the management of these infants.

2. Sickle Cell Disease (SS) and other serious Hemoglobinopathies

a) Immediately upon obtaining the initial positive screening result, presumptive of SS or other serious hemoglobinopathy, the Department shall notify the Collector, who shall be responsible for insuring that prompt follow-up diagnostic testing is conducted.

b) Appropriate, expectant medical management shall not be withheld pending the confirmatory test results for either SS or other related hemoglobinopathy. Therefore, non-physician Collector shall immediately refer the infant for appropriate medical intervention. It is recommended that a pediatric hematologist consultant be utilized in the management of these infants.

c) Immediately upon obtaining an initial positive screening, presumptive of trait, the Department shall notify the Collector in writing. The parent shall be notified in writing by the Department.

SECTION VII. ARKANSAS DEPARTMENT OF HEALTH ROLE IN TREATMENT AND MONITORING

A. Listing of Consultants

1. For Phenylketonuria (PKU), Congenital Hypothyroidism (CH), Galactosemia, Sickle Cell Disease and other hemoglobinopathies, Biotinidase Deficiency (BIOT), Congenital Adrenal Hyperplasia (CAH), Cystic Fibrosis (CF), Amino Acid Disorders, Fatty Acid Oxidation Disorders, Organic Acid Disorders, Severe Combined Immunodeficiency (SCID), the Department shall maintain a list of pediatric consultants having special competence in these disorders, and shall make the names of such consultants known to the attending physicians of infants with abnormal screening test results.

B. Registry

1. For Phenylketonuria (PKU), Congenital Hypothyroidism (CH), Galactosemias, Sickle Cell Disease (SS), and other hemoglobinopathies, Biotinidase Deficiency (BIOT), Congenital Adrenal Hyperplasia (CAH), Cystic Fibrosis (CF), Amino Acid Disorders, Fatty Acid Oxidation Disorders, Organic Acid Disorders, Severe Combined Immunodeficiency (SCID), the Department shall maintain a registry to record laboratory results and diagnoses of all tested infants, and to track referral for those infants in whom abnormal findings were noted during the screening process.

C. Nutritional Therapy

1. Phenylketonuria (PKU)

a) Nutritional therapy with low phenylalanine formula and/or foods shall be instituted after the diagnosis of PKU.

2. Galactosemia

a) Nutritional therapy with lactose-free formula and/or foods shall be instituted after the diagnosis of Galactosemia.

3. Other genetic conditions

a) Other genetic conditions discovered by the laboratory testing done pursuant to these regulations may require nutritional therapy as recommended by specialist consultants.

SECTION VIII. SEVERABILITY

If any provision of these Rules, or application thereof to any person or circumstance is held invalid, such invalidity shall not affect other provisions or applications of these Rules which give effect without the invalid provisions or applications, and to this end the provisions here to are declared to be severable.

SECTION IX. REPEAL

All Rules and parts of Rules in conflict here with are hereby repealed.

CERTIFICATION

This will certify the foregoing Rules Pertaining to Testing of Newborn Infants were adopted by the Arkansas State Board of Health at a regular session of the Board held in Arkansas on the 24th day of October, 2019.

Nathaniel Smith, MD, MPH
Secretary of Health
Secretary, Arkansas State Board of Health

QUESTIONNAIRE FOR FILING PROPOSED RULES WITH THE ARKANSAS LEGISLATIVE COUNCIL

DEPARTMENT/AGENCY Department of Health
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DIVISION DIRECTOR Dr. Glen Baker
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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.healthyarkansas.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 X 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 X 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_____	General Revenue_____
Federal Funds_____	Federal Funds_____
Cash Funds_____	Cash Funds_____
Special Revenue_____	Special Revenue_____
Other (Identify)_____	Other (Identify)_____
Total_____	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____	General Revenue____$63, 987_____
Federal Funds_____$80,114 ____	Federal Funds_____$161,083_____
Cash Funds_____	Cash Funds_____
Special Revenue_____	Special Revenue_____
Other (Identify)_____	Other (Identify)_____
Total_____$112, 535_____	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.