DEPARTMENT OF HEALTH, STATE BOARD OF HEALTH

SUBJECT: Rules Pertaining to the Testing of Newborn Infants

DESCRIPTION: The Rules Pertaining to Testing of Newborn Infants are duly adopted and promulgated by the Arkansas Board of Health pursuant to the authority expressly conferred by the laws of the State of Arkansas including, without limitation, Ark. Code Ann. § 20-15-301, et seq.

Act 490 of 2023 required amendments to the Rules Pertaining to Testing of Newborn Infants, specifically amending the list of conditions which require screenings to match those core medical conditions listed in the recommended uniform screening panel by the United States Secretary of Health and Human Services.

The following changes are proposed:

- Removed definitions 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, MPS1 spectrum of disease, and childhood onset (cerebral) X-ALD.
- Amended the list of required screenings to match the recommended uniform screening panel by the United States Secretary of Health and Human Services.
- Amended the reporting requirements for positive screening results, and the required follow up with appropriate specialists based on the screening results.

PUBLIC COMMENT: No public hearing was held on these rules. The public comment period expired on November 19, 2023. The agency indicated that it received no public comments.

Lacey Johnson, an attorney with the Bureau of Legislative Research, asked the following question and received the following response:

Q. Section VI.B.1 of the rules states that the Department, in collaboration with consulting medical specialists, "shall define the levels which constitute positive screening results for each core medical condition." Where are these levels defined? Is this something that will come through the rulemaking process?

RESPONSE: Per Katie Seely, PhD, HCLD (ABB), Director, Glen F. Baker Public Health Laboratory, in regard to setting "levels", these are condition specific. The levels are adjusted on a regular basis due to statistics. Depending on the analysis, some levels are changed daily.

Thus, the levels should not be "defined" or set in stone, since they can change often. This is considered normal laboratory practice with newborn screening analysis.

The proposed effective date is pending legislative review and approval.

FINANCIAL IMPACT: The agency indicated that this rule has no financial impact.

LEGAL AUTHORIZATION: The Department of Health has authority to prescribe tests to be administered to newborn infants. *See* Ark. Code Ann. § 20-15-304(2). It also has authority to promulgate rules relating to "[w]hat persons and institutions shall be required to obtain specimens from newborn infants . . .; [t]he amount to be charged by the central laboratory for processing the specimens; and [t]he method of billing the charges to the persons and institutions[.]" Ark. Code Ann. § 20-15-304(3).

This rule implements Act 490 of 2023. The Act, sponsored by Representative Aaron Pilkington, created the Universal Newborn Screening Act and ensured that newborns are screened for conditions recommended by the United States Department of Health and Human Services.

Arkansas Department of Health

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

Governor Sarah Huckabee Sanders

Renee Mallory, RN, BSN, Secretary of Health

Jennifer Dillaha, MD, Director

PROPOSED REVISIONS TO RULES PERTAINING TO TESTING OF NEWBORN INFANTS

PURPOSE

The Arkansas Department of Health (Department) is seeking Governor Sanders's review of proposed amendments to the Rules Pertaining to Testing of Newborn Infants.

BACKGROUND

Pursuant to A.C.A. §20-15-301, et seq., the Department has authority to promulgate the Rules Pertaining to Testing of Newborn Infants. These rules protect the health and safety of newborns by ensuring all infants born in Arkansas have the opportunity to be screened for core medical conditions.

KEY POINTS

The proposed amendments are to makes changes to comply with Acts 490 of 2023.

DISCUSSION

The Rules Pertaining to Testing of Newborn Infants are duly adopted and promulgated by the Arkansas Board of Health pursuant to the authority expressly conferred by the laws of the State of Arkansas including, without limitation, Ark. Code Ann. §20-15-301, et seq.

Act 490 of 2023 required amendments to the Rules Pertaining to Testing of Newborn Infants, specifically amending the list of conditions which require screenings to match those core medical conditions listed in the recommended uniform screening panel by the United States Secretary of Health and Human Services.

The following changes are proposed:

- Removed definitions 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.
- Amended the list of required screenings to match the recommended uniform screening panel by the United States Secretary of Health and Human Services.
- Amended the reporting requirements for positive screening results, and the required follow up with appropriate specialists based on the screening results.

QUESTIONNAIRE FOR FILING PROPOSED RULES WITH THE ARKANSAS LEGISLATIVE COUNCIL

DEPARTMENT Arkansas Department of Health
BOARD/COMMISSION Public Health Laboratory
BOARD/COMMISSION DIRECTOR Dr. Katie Seely
CONTACT PERSON Laura Shue, General Counsel
ADDRESS 4815 West Markham Street, Slot 31, Little Rock, AR 72205
PHONE NO. (501) 661-2297 **EMAIL** Laura.Shue@arkansas.gov
NAME OF PRESENTER(S) AT SUBCOMMITTEE MEETING
Laura Shue; Dr. Katie Seely
PRESENTER EMAIL(S) Laura.Shue@arkansas.gov; Katie.Seely@arkansas.gov

INSTRUCTIONS

In order to file a proposed rule for legislative review and approval, please submit this Legislative Questionnaire and Financial Impact Statement, and attach (1) a summary of the rule, describing what the rule does, the rule changes being proposed, and the reason for those changes; (2) both a markup and clean copy of the rule; and (3) all documents required by the Questionnaire.

If the rule is being filed for permanent promulgation, please email these items to the attention of Rebecca Miller-Rice, miller-ricer@blr.arkansas.gov, for submission to the Administrative Rules Subcommittee.

If the rule is being filed for emergency promulgation, please email these items to the attention of Director Marty Garrity, garritym@blr.arkansas.gov, for submission to the Executive Subcommittee.

Please answer each question completely using layman terms.

****

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

2. What is the subject of the proposed rule? Screening requirements for newborn infants of core medical condi

3. Is this rule being filed under the emergency provisions of the Arkansas Administrative Procedure Act? Yes ☐ No ☑

If yes, please attach the statement required by Ark. Code Ann. § 25-15-204(c)(1).

If yes, will this emergency rule be promulgated under the permanent provisions of the Arkansas Administrative Procedure Act? Yes ☐ No ☐

4. Is this rule being filed for permanent promulgation? Yes ☑ No ☐

If yes, was this rule previously reviewed and approved under the emergency provisions of the Arkansas Administrative Procedure Act? Yes ☐ No ☐

If yes, what was the effective date of the emergency rule? _____

On what date does the emergency rule expire?_____

5. Is this rule required to comply with a *federal* statute, rule, or regulation? Yes ☐ No ☑

If yes, please provide the federal statute, rule, and/or regulation citation.

6. Is this rule required to comply with a *state* statute or rule? Yes ☑ No ☐

If yes, please provide the state statute and/or rule citation.

Act 490 of 2023.

7. Are two (2) rules being repealed in accord with Executive Order 23-02? Yes ☐ No ☑

If yes, please list the rules being repealed.
If no, please explain.

The proposed amends to the Rules Pertaining to Testing of Newborn Infants are to comply with Act 490 of 2023, updating the conditions for which testing is required and to update protocols for following up on screenings.

8. Is this a new rule? Yes ☐ No ☑

Does this repeal an existing rule? Yes ☐ No ☑
If yes, the proposed repeal should be designated by strikethrough. If it is being replaced with a new rule, please attach both the proposed rule to be repealed and the replacement rule.

Is this an amendment to an existing rule? Yes ☑ No ☐
If yes, all changes should be indicated by strikethrough and underline. In addition, please be sure to label the markup copy clearly as the markup.

9. What is the state law that grants the agency its rulemaking authority for the proposed rule, outside of the Arkansas Administrative Procedure Act? Please provide the specific Arkansas Code citation(s), including subsection(s).

Ark. Code Ann. §20-15-301, et seq.

10. Is the proposed rule the result of any recent legislation by the Arkansas General Assembly?
Yes ☑ No ☐

If yes, please provide the year of the act(s) and act number(s).

Act 490 of 2023

11. What is the reason for this proposed rule? Why is it necessary?

The proposed amends to the Rules Pertaining to Testing of Newborn Infants are to comply with Act 490 of 2023, updating the conditions for which testing is required and to update protocols for following up on screenings.

12. Please provide the web address by which the proposed rule can be accessed by the public as provided in Ark. Code Ann. § 25-19-108(b)(1).

https://www.healthy.arkansas.gov/proposed-amendment-to-existing-rules

13. Will a public hearing be held on this proposed rule? Yes ☐ No ☑

If yes, please complete the following:

Date: _____

Time: _____

Place: _____

Please be sure to advise Bureau Staff if this information changes for any reason.

14. On what date does the public comment period expire for the permanent promulgation of the rule? Please provide the specific date. 11/19/2023

15. What is the proposed effective date for this rule? 1/1/2024

16. Please attach (1) a copy of the notice required under Ark. Code Ann. § 25-15-204(a)(1) and (2) proof of the publication of that notice.

17. Please attach proof of filing the rule with the Secretary of State, as required by Ark. Code Ann. § 25-15-204(e)(1)(A).

18. Please give the names of persons, groups, or organizations that you anticipate will comment on these rules. Please also provide their position (for or against), if known.

19. Is the rule expected to be controversial? Yes ☐ No ☑

If yes, please explain.

FINANCIAL IMPACT STATEMENT

PLEASE ANSWER ALL QUESTIONS COMPLETELY.

DEPARTMENT Arkansas Department of Health
BOARD/COMMISSION Public Health Laboratory
PERSON COMPLETING THIS STATEMENT Laura Shue, General Counsel
TELEPHONE NO. (501) 661-2297 **EMAIL** Laura.Shue@arkansas.gov

To comply with Ark. Code Ann. § 25-15-204(e), please complete the Financial Impact Statement and email it with the questionnaire, summary, markup and clean copy of the rule, and other documents. Please attach additional pages, if necessary.

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 ☑ No ☐

   If no, please explain:

   (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 reason for adoption of the more costly rule is based on the interests of public health, safety, or welfare, and if so, how; and

   (d) whether the reason for adoption of the more costly rule is within the scope of the agency's statutory authority, and if so, how.

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 $0.00	Total $0.00

(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 $0.00	Total $0.00

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

Current Fiscal Year	**Next Fiscal Year**
$_____	$_____

6. What is the total estimated cost by fiscal year to a state, county, or 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.

NOTICE OF PUBLIC COMMENT PERIOD

The Arkansas Department of Health (ADH) is accepting public comments on the Act 490 of 2023 which amends Rules Pertaining to Testing of Newborn Infants from October 20, 2023 thru November 19, 2023. The comment period is provided to allow interested parties and the public to provide any comments. The proposed rule revision with a summary of changes can be viewed online at https://www.healthy.arkansas.gov/proposed-amendment-to-existing-rules or you may request a copy from our office at Arkansas Department of Health-Glen F. Baker, M.D. Public Health Laboratory-NewBorn Screening Section-Ms. Jomeka Edwards 501-661-2445.

Comments on the proposed changes can also be mailed to Arkansas Department of Health, Comments/ADH-Public Health Laboratory-NewBorn Screening Section/SLOT 47, 4815 West Markham, Little Rock Arkansas, 72205, or emailed to Jomeka.edwards@arkansas.gov.

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 _____

Arkansas Department of Health
Renee Mallory, RN, BSN,
Interim Secretary of Health

Jennifer Dillaha, MD
Director and State Health Officer

Table of Contents

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.~~

A. 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.

B. **Recommended uniform screening panel (RUSP)** is a list of medical conditions that the Secretary of the Department of Health and Human Services (HHS) recommends for states to screen as part of their state NBS programs. Although states ultimately determine what medical conditions their NBS programs will screen for, the RUSP establishes a standardized list of medical conditions that have been supported by the Advisory Committee on Heritable Disorders in Newborns and Children and recommended by the Secretary of HHS. Medical conditions on the RUSP are chosen based on evidence that supports the potential net benefit of screening, the ability of states to screen for the condition, and the availability of effective treatments. Medical conditions included on the RUSP are designated as Core Conditions or Secondary Conditions.

~~K.~~C. **Universal newborn screening program (NBS)** is a public health intervention program with the goal of supporting early diagnosis, treatment, and services for many life-threatening genetic illnesses before any symptoms begin to enable healthy development and prevention of disability or morbidity.

~~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~~the core medical conditions as listed in the RUSP.

A. These Rules provide a method to assure that:

1. All newborn infants are screened for core medical conditions included in the RUSP.~~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, 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~~ screening results shall 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~~, as amended by Act 490 of 2023.

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 State 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 core medical conditions as listed in the RUSP ~~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 core medical conditions as listed in the RUSP~~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 of Health: The Department of Health'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 of Health.

2. The State 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. Testing for core medical conditions newly added to the RUSP shall begin within thirty-six (36) months upon introduction to the RUSP.

D. Follow-Up

1. The Department of Health 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 a core medical condition as listed on the RUSP, ~~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~~condition. It is strongly recommended that consultation be obtained with a physician who has special competence in the management of these ~~disorders~~conditions.

(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~~ conditions 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~~conditions.

SECTION V. SPECIMEN COLLECTION AND SUBMISSION

A. The blood specimen for core medical conditions as listed in the RUSP screening~~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 I 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~~ Laboratory at:

Arkansas Department of Health
Public Health Laboratory
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)~~

~~2.~~1.The Department of Health, in collaboration with consulting medical specialists providing clinical advice on core medical conditions, shall define the ~~phenylalanine~~ levels which constitute~~s a~~ positive screening results for each core medical condition listed in the RUSP and included in the Arkansas NBS screening panel~~PKU~~.

~~(a) An infant whose phenylalanine level is determined by the Department to be negative for PKU requires no action to be taken. However, attending physicians~~

~~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.~~

~~3. 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.~~

~~4. 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.~~

~~5.~~2. The medical caretaker shall give special consideration to retesting any infant whose case findings, testing circumstances, or family history seems to medically warrant it.

~~6. 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.~~

~~7. 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).~~

~~2.~~1. Immediately upon obtaining the initial positive screening result, the Department of Health shall notify the attending physician or medical attendant, who shall be responsible for ensuring that prompt follow-up diagnostic testing is conducted.

~~3.~~2. 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, or other appropriate specialist consultant, depending on the medical condition, be utilized in the management of these infants.

~~4. 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 core medical conditions, as listed on the RUSP, ~~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 of Health 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 core medical conditions, as listed on the RUSP, ~~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 of Health 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)

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

2. Galactosemia

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

3. Other genetic conditions

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 Newborn Screening were adopted by the Arkansas State Board of Health at a regular session of the Board held in Arkansas on the _____ day of _____, 2023. The effective date of this rule shall _____.

_____
Jennifer Dillaha, MD
Secretary of Arkansas State Board of Health
Director of the Arkansas Department of Health

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.

Effective _____

Arkansas Department of Health
Renee Mallory, RN, BSN,
Interim Secretary of Health

Jennifer Dillaha, MD
Director and State Health Officer

RULES PERTAINING TO TESTING OF NEWBORN INFANTS

Table of Contents

SECTION I. DEFINITIONS.

A. 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 are described in SECTION IV.A.

B. **Recommended uniform screening panel (RUSP)** is a list of medical conditions that the Secretary of the Department of Health and Human Services (HHS) recommends for states to screen as part of their state NBS programs. Although states ultimately determine what medical conditions their NBS programs will screen for, the RUSP establishes a standardized list of medical conditions that have been supported by the Advisory Committee on Heritable Disorders in Newborns and Children and recommended by the Secretary of HHS. Medical conditions on the RUSP are chosen based on evidence that supports the potential net benefit of screening, the ability of states to screen for the condition, and the availability of effective treatments. Medical conditions included on the RUSP are designated as Core Conditions or Secondary Conditions.

C. **Universal newborn screening program (NBS)** is a public health intervention program with the goal of supporting early diagnosis, treatment, and services for many life-threatening genetic illnesses before any symptoms begin to enable healthy development and prevention of disability or morbidity.

SECTION II. PURPOSE.

The purpose of these Rules is to assure that all infants born in Arkansas have the opportunity to be screened for the core medical conditions as listed in the RUSP.

A. These Rules provide a method to assure that:

1. All newborn infants are screened for core medical conditions included in the RUSP.

2. All newborns with abnormal screening results shall 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., as amended by Act 490 of 2023.

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 State 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 core medical conditions as listed in the

RUSP 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 Department of Health 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 core medical conditions as listed in the RUSP, 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 of Health: The Department of Health'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 of Health.

2. The State 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. Testing for core medical conditions newly added to the RUSP shall begin within thirty-six (36) months upon introduction to the RUSP.

D. Follow-Up

1. The Department of Health 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 a core medical condition as listed on the RUSP, the Department shall consult with specialist physicians. 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 condition. It is strongly recommended that consultation be obtained with a physician who has special competence in the management of these conditions.

   (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 conditions in collaboration with medical specialists. 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 conditions.

SECTION V. SPECIMEN COLLECTION AND SUBMISSION

A. The blood specimen for core medical conditions as listed in the RUSP screening 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.

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_____
Jennifer Dillaha, MD
Secretary of Arkansas State Board of Health
Director of the Arkansas Department of Health

Arkansas Department of Health

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

Governor Sarah Huckabee Sanders

Renee Mallory, RN, BSN, Secretary of Health

Jennifer Dillaha, MD, Director

PUBLIC COMMENT REPORT

Proposed Rules Pertaining to Testing of Newborn Infants

PUBLIC COMMENTS:

Public comment period expired November 27, 2023.
No comments received.

AGENCY RESPONSE:
Proceed to adoption.