ARKANSAS REGISTER

Transmittal Sheet

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Effective Date _____ Code Number _____

Name of Agency Arkansas Department of Health

Department Public Health Laboratory

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

Rule Title: Rules Pertaining to the Testing of Newborn Infants

Intended Effective Date (Check One)

- ☐ Emergency (ACA 25-15-204)
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Electronic Copy of Rule e-mailed from: (Required under ACA 25-15-218)

Laura Shue	Laura.Shue@arkansas.gov	01/31/2024
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

01/31/2024
Date

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 February 10, 2024

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

Jennifer Dillaha, MD
Director and State Health Officer
Secretary of the Arkansas State Board of Health

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.

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

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.

C. Reporting of Results

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.

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

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, 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, 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 27th day of July, 2023. The effective date of this rule shall 10th day of February, 2024.

Jennifer Dillaha, MD

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