

**Title 20. Public Health and Welfare**  
**Chapter I. Generally, Department of Health**  
**Subchapter D. Immunization and Disease**  
**Part 107. Rules Pertaining to Testing of Newborn Infants**

**Codification Notes.** This part as promulgated prior to codification into the Code of Arkansas Rules provided as follows:

"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 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."

"Effective February 10, 2024"

**Subpart 1. Generally**

**20 CAR § 107-101. Purpose.**

(a) The purpose of this part is to ensure that all infants born in Arkansas have the opportunity to be screened for the core medical conditions as listed in the RUSP.

(b) This part provides a method to ensure that all:

(1) Newborn infants are screened for core medical conditions included in the RUSP; and

(2) Newborns with abnormal screening results shall receive appropriate medical follow-up.

**Authority.** Arkansas Code § 20-15-304.

**20 CAR § 107-102. Definitions.**

As used in this part:

(1)(A) The “collector” means the person or party responsible for collecting and submitting the blood specimen for testing.

(B) The persons or parties who are collectors under this part are described in 20 CAR § 107-103(a);

(2)(A) “Recommended uniform screening panel (RUSP)” is a list of medical conditions that the Secretary of the Department of Health and Human Services recommends for states to screen as part of their state NBS programs.

(B) 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:

(i) Supported by the Advisory Committee on Heritable Disorders in Newborns and Children; and

(ii) Recommended by the Secretary of the Department of Health and Human Services.

(C) Medical conditions on the RUSP are chosen based on evidence that supports the:

(i) Potential net benefit of screening;

(ii) Ability of states to screen for the condition; and

(iii) Availability of effective treatments.

(D) Medical conditions included on the RUSP are designated as Core Conditions or Secondary Conditions; and

(3) "Universal newborn screening program (NBS)" is a public health intervention program with the goal of supporting early diagnosis, treatment, and services:

- (A) For many life-threatening genetic illnesses before any symptoms begin; and
- (B) To enable healthy development and prevention of disability or morbidity.

**Authority.** Arkansas Code § 20-15-304.

**20 CAR § 107-103. Responsibility.**

**(a) Collection and submission.**

**(1) Medical facilities/medical staff.**

(A) 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 ensure that blood tests for core medical conditions as listed in the RUSP are conducted and processed in accordance with this part.

(B) The licensed facility shall also be responsible for submission of the usable blood specimen in cases where:

(i) An infant less than six (6) months of age is admitted (i.e., born out of hospital, neonatal transfer, etc.); and

(ii) It is brought to the attention of the facility or the attending physician that the infant is untested.

(C)(i) 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.

(ii) The discharging facility and attending physician shall notify the Department of Health within one (1) week of discharge if their efforts fail to arrange for testing.

(2) **Physicians.** Physicians assuming care of infants who are under six (6) months of age and who come to their attention as being untested or inadequately tested for core conditions as listed in the RUSP shall also be responsible for ensuring collection and submission of usable blood specimens for these infants.

(3) **Licensed midwives.**

(A) 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:

(i) Conducting newborn screening; and

(ii) Documenting that a blood sample is obtained after twenty-four (24) hours and no later than seventy-two (72) hours after birth.

(B) 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.**

(A) **The department.** The department's Local Health Unit shall collect and submit usable blood specimens on all infants under six (6) months of age who come to their attention as being tested or inadequately tested.

(B) 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 thirty-one dollars (\$131) for the processing and testing of newborn screening specimens by the department.

(2) The board 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.

(2) 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)(A) The department shall be responsible for the interpretation of laboratory results and the reporting of abnormal results to the attending physician or birth attendant.

(B) If the screening result is suggestive of a core medical condition as listed on the RUSP, the department shall consult with specialist physicians.

(C) 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)(i) 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.

(ii) It is strongly recommended that consultation be obtained with a physician who has special competence in the management of these conditions.

(B)(i) The attending physician or other responsible healthcare provider who conducts testing in follow-up to abnormal screens shall report subsequent test results, whether negative or positive, to the department.

(ii) To provide for long-term follow-up the department will collect data on affected infants each year for five (5) years to determine healthcare maintenance and health status, especially the presence of intellectual disability or permanent disability.

(iii) The department will establish protocols for follow-up of all screened conditions in collaboration with medical specialists.

(iv) 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.

**Authority.** Arkansas Code § 20-15-304.

**20 CAR § 107-104. Specimen collection and submissions.**

(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)(A) For all healthy infants born in medical facilities, the specimen shall be collected before the time of discharge from the facility.

(B) Optimum time for collection is twenty-four (24) to seventy-two (72) hours after birth, and all collectors should strive to comply with that time frame.

(C) If any infant is discharged or specimen collected prior to twenty-four (24) hours of age, a repeat test shall be arranged by the medical facility and the attending physician.

(D) This repeat specimen shall be collected by the infant's seventh day of life.

(E) A repeat test for sickle cell disease shall not be required if specimen was collected prior to twenty-four (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)(A) Specimens from infants not born in medical facilities shall be collected between twenty-four (24) and seventy-two (72) hours after birth.

(B) Infants under six (6) 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 Department of Health Public Health Laboratory, Little Rock, Arkansas, no later than one (1) business day from collection.

(2) Specimens are submitted only on forms provided by the Public Health Laboratory.

(3) 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

(2) 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.

(2) The collector shall be responsible for ensuring recollection and resubmission within seven (7) calendar days of notification.

**Authority.** Arkansas Code § 20-15-304.

**20 CAR § 107-105. Analysis, interpretation, and reporting of results.**

(a) **Laboratory analysis.**

(1) All specimens received by the laboratory shall be initially examined within five (5) working days of receipt.

(2) Abnormal results shall be reported to the collector within two (2) 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:

(A) Listed in the RUSP; and

(B) 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 shall notify the attending physician or medical attendant, who shall be responsible for ensuring that prompt follow-up diagnostic testing is conducted.

(2)(A) Appropriate, expectant medical management shall not be withheld pending the confirmatory test results.

(B) A nonphysician collector shall immediately refer the infant for appropriate medical intervention.

(C) 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.

**Authority.** Arkansas Code § 20-15-304.

**20 CAR § 107-106. Department of Health role in treatment and monitoring.**

(a) **Listing of consultants.** For core medical conditions, as listed on the RUSP, the Department of Health shall:

(1) Maintain a list of pediatric consultants having special competence in these disorders; and

(2) Make the names of such consultants known to the attending physicians of infants with abnormal screening test results.

(b) **Registry.** For core medical conditions, as listed on the RUSP, the department shall maintain a registry to:

- (1) Record laboratory results and diagnoses of all tested infants; and
- (2) 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 this part may require nutritional therapy as recommended by specialist consultants.

**Authority.** Arkansas Code § 20-15-304.

**20 CAR § 107-107. Repeal.**

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

**Authority.** Arkansas Code § 20-15-304.