ARKANSAS REGISTER

Transmittal Sheet

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Secretary of State
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Name of Agency Arkansas Department of Health

Department Section of Maternal and Child Health

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Statutory Authority for Promulgating Rules Act 192 of 1967

Intended Effective Date

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CERTIFICATION OF AUTHORIZED OFFICER

I Hereby Certify That The Attached Rules Were Adopted In Compliance With Act 434 of 1967 As Amended.

SIGNATURE

Director
TITLE

11/5/92
DATE

007.13.92--002

SEVERABILITY

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

REPEAL

All Regulations and parts of Regulations in conflict herewith are hereby repealed.

CERTIFICATION

This will certify the foregoing Rules and Regulations pertaining to Newborn Screening were adopted by the Arkansas State Board of Health at a regular session of the Board held in Little Rock on the 22 Day of October, 1992 and after a Public Hearing on the 22 Day of April, 1992 held in Little Rock, Arkansas, at the State Health Building.

M. Joycelyn Elders
Secretary
Arkansas Board of Health

The foregoing Amendments having been filed in my office are hereby adopted on this 3rd Day of November, 1992

Bill Clinton
Governor

007.13.92-002

RULES & REGULATIONS
PERTAINING TO THE TESTING OF NEWBORN INFANTS
FOR PHENYLKETONURIA, CONGENITAL HYPOTHYROIDISM
AND SICKLE CELL ANEMIA

1. PURPOSE

Phenylketonuria (PKU) and Congenital Hypothyroidism (CH) 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. Early diagnosis and treatment are absolutely essential in order to avoid these health problems.

Sickle Cell Disease (SS) is the most common inherited hemoglobinopathy that may cause serious disease even in the first few months of life. This disease occurs almost exclusively in Blacks, Orientals, and people of Mediterranean descent. The disease causes anemia, lowered resistance to infection, and is associated with an increased morbidity and mortality unless diagnosed and treated early.

Sickle Cell Trait (AS) occurs in about 8 to 10% of Black Americans. Persons with the trait are usually healthy and experience a normal lifespan. However, they can pass this gene on to their offspring. Children born to 2 people who have the trait have a 25% chance of having Sickle Cell disease.

These Rules and Regulations provide a method to assure that:

a. All newborn infants are tested for PKU and CH and all newborns with an abnormal screen receive appropriate medical follow-up.

b. All non-caucasian newborn infants are tested for sickle cell anemia and all newborns with an abnormal test receive appropriate medical follow-up.

2. AUTHORITY

These Rules and Regulations are promulgated pursuant to the authority conferred by Act 192 of 1967, the same being Arkansas code annotated 20-15-301 et. seq.

3. 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 ensure that blood tests for PKU, CH, and Sickle Cell Anemia are conducted and processed in accordance with these rules and regulations. 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 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 PKU, CH, and Sickle Cell Anemia shall also be responsible for assuring collection and submission of usable blood specimens for these infants.

(3) Birth Attendants: In cases where the birth occurs outside a licensed medical facility, it shall be the responsibility of the birth attendant to ensure that a usable blood specimen is collected and submitted.

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

(B) Payment

(1) The submitter will be charged a fee for the processing of newborn screening specimens by the Arkansas Department of Health.

(2) The Board of Health may determine the amount of this fee based on the Arkansas Department of Health cost to process the specimens.

(C) Laboratory Analysis

The Arkansas Department of Health 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) Arkansas Department of Health: The Arkansas Department of Health shall be responsible for the interpretation of laboratory results and the reporting of abnormal results to the submitter of the blood specimen. If the screening result is suggestive of Classical or Variant PKU, or Sickle Cell Anemia, the Department of Health shall request the parent or guardian's permission to notify relevant, statewide clinical and/or research programs of the child's diagnosis and identity. A tracking system for infants identified with PKU, CH, and Sickle Cell Anemia shall be maintained in order to evaluate program operations and medical outcome.

(2) Submitter:

a. Upon receipt of a notice of an abnormal test result for PKU or CH, each submitter shall be responsible for the appropriate medical treatment, referral, and/or retesting within seven (7) days of notification. It is strongly recommended that an endocrinologist/geneticist be consulted.

b. Upon receipt of notice of an abnormal test for Sickle Cell Anemia, each submitter shall be responsible for the appropriate retesting, medical treatment, and/or referral. It is strongly recommended that a pediatric hematologist be consulted.

4. SPECIMEN COLLECTION AND SUBMISSION

The blood specimen for PKU, CH, and Sickle Cell Anemia testing must be collected and submitted as described below:

(A) Timing of Specimen Collection

(1) For all healthy infants born in medical facilities, the specimen shall be collected at the time of discharge from the facility or within seven days of birth, whichever is sooner. However, if any infant is discharged or specimen collected prior to 24 hours of age, a repeat test for PKU and CH 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 Anemia 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 the second and seventh day of life.

(4) 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.

(B) Submission of Specimens

Specimens shall be submitted to the Division of Public Health Laboratories, Arkansas Department of Health, Little Rock, Arkansas within 48 hours of collection. Specimens are submitted only on forms provided by the Department of Health laboratory. The submitter is responsible for supplying adequate identifying information on the collection/report form to be used for tracking infants with abnormal screening results.

(C) Forms

Submission forms may be obtained by writing to:

Public Health Laboratories
Arkansas Department of Health
4815 West Markham Street
Little Rock, AR 72205

The county health units will not supply these forms.

(D) Unusable Specimens

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

5. ARKANSAS DEPARTMENT OF HEALTH LABORATORY ANALYSIS, INTERPRETATION, AND REPORTING OF RESULTS

(A) Laboratory Analysis

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

(B) Interpretation of Results

(1) Phenylketonuria (PKU)

a. The Arkansas Department of Health shall define the phenylalanine level which constitutes a positive screening result for PKU. This level shall be determined based on current state of the art standards and practices.

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

(2) Congenital Hypothyroidism (CH)

a. The Arkansas Department of Health shall define the thyroxine and thyroid stimulating hormone levels which constitute positive screening results for CH. These levels shall be determined based on current state of the art standards and practices.

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) Sickle Cell Anemia or Trait

a. The Arkansas Department of Health shall define the laboratory value which constitutes a positive screening result for SS, AS or other related hemoglobinopathy. This value shall be based on the current state of the art, standards, and practices.

b. An infant whose hemoglobin is determined by the Arkansas Department of Health to be negative for SS or other related hemoglobinopathies requires no special action.

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

(C) Reporting of Results

(1) Phenylketonuria (PKU) and Congenital Hypothyroidism (CH)

a) Immediately upon obtaining the initial positive screening result, the Department of Health shall notify the submitter, 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 PKU or CH. Therefore, a non-physician submitter shall immediately refer the infant for appropriate medical intervention. It is recommended that a pediatric geneticist or endocrinologist consultant be utilized in the management of these infants.

(2) Sickle Cell Anemia

(a) Immediately upon obtaining the initial positive screening result, presumptive of SS or other related hemoglobinopathy, the Department of Health shall notify the submitter, 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, a non-physician submitter 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 of Health shall notify the submitter in writing. The parent shall be notified in writing by the Department of Health.

6. ARKANSAS DEPARTMENT OF HEALTH'S ROLE IN TREATMENT AND MONITORING

(A) Listing of Consultants

(1) Phenylketonuria (PKU) and Congenital Hypothyroidism (CH)

The Department of Health shall maintain a list of assenting consultants in pediatric endocrinology or genetics for PKU and CH, and shall make the names of such physicians known to the attending physicians of infants with abnormal screening test results.

(2) Sickle Cell Anemia

The Department of Health shall maintain a list of assenting consultants in pediatric hematology and shall make the names of such physicians known to the attending physicians of infants with positive test results.

(B) Registry

(1) Phenylketonuria (PKU) and Congenital Hypothyroidism (CH)

The Department of Health shall also maintain a registry to record the results of diagnosis and to track referral for those infants in whom abnormal findings were noted during the screening process.

(2) Sickle Cell Anemia

The Department of Health shall maintain a registry to record the results of diagnosis and to track referral for those infants in whom the disease was 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. Nutritional counseling and low phenylalanine formula may be provided by the Department of Health, under the direction of a physician.

7. SEVERABILITY

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