

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
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RULES PERTAINING TO TESTING OF NEWBORN INFANTS

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SECTION I. DEFINITIONS.

- A. **Phenylketonuria (PKU), Congenital Hypothyroidism (CH) and Galactosemia** are conditions (diseases) which cause irreversible brain damage and mental retardation unless they are detected and treated at a very early stage in the life of a newborn individual. Untreated Galactosemia also results in liver disease, cataracts, and increased susceptibility to serious infection. Early diagnosis and treatment are absolutely essential in order to avoid these health problems.
- B. **Sickle Cell Disease (SS)** is the most common inherited abnormality of a red blood cell protein called hemoglobin. It is caused by a genetic abnormality that must be inherited from both parents. Sickle Cell Disease may cause serious health problems even in the first few months of life. It occurs much more commonly in people of African American, Asian and Mediterranean descent. In addition to the anemia, it lowers resistance to infection, and is associated with increased morbidity and mortality unless diagnosed and treated early. Sickle Cell Disease is one of a handful of related hemoglobinopathies each of which can cause similar health problems with varying severity.
- C. **Sickle Cell Trait (AS)** and other hemoglobinopathy traits differ from their corresponding diseases. Traits occur when the genetic abnormality is inherited from only one parent, the other parent contributing a normal gene. Hemoglobinopathy traits cause only minor health issues that show up occasionally in life. They are associated with normal life-spans. Sickle Cell Trait (AS) is the most common, occurring in 8 to 10% of African-Americans.
- D. **Biotinidase Deficiency (BIOT)** is caused by the lack of an enzyme called biotinidase, resulting in an inability of the body to use Vitamin B substances absorbed by the intestines. Without sufficient biotin, several other critical enzyme systems are unable to function properly. Biotinidase deficiency can lead to seizures, developmental delay, skin rash, and hearing loss. Newborns with the disorder appear normal but develop critical symptoms after the first weeks or months of life. Symptoms include floppiness, seizures, developmental delay, hair loss, rashes, hearing loss and vision loss. Metabolic acidosis can result in coma and death. A daily biotin dietary supplement can prevent all symptoms.
- E. **Congenital Adrenal Hyperplasia (CAH)** is a group of disorders caused by the deficiency of an adrenal enzyme resulting in decreased production of important hormones called cortisol and aldosterone. Cortisol helps the body respond to stressful events. Aldosterone helps the body maintain its fluids and salts. Without enough of these hormones, the affected newborn may appear normal, but can quickly develop symptoms including lethargy, vomiting, muscle weakness and dehydration. In severe cases death may occur within a few weeks if left untreated. One kind of CAH may show up first as ambiguous genitalia in the newborn. Infants with milder forms of the disorder are still at risk for reproductive and growth difficulties. If detected early and maintained on appropriate doses of medication, infants diagnosed with CAH can have normal growth and development.

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- ~~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.

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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), Congenital~~

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~~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.

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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 I 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:

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- (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, Galactosemia, 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.

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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 constitutes ~~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~~

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~~shall give special consideration when testing circumstances or infant evaluation/family history suggests the possibility of need for prescreening in cases where PKU or 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 Galactosemia 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).~~

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- ~~(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 Hypothyroidism (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~~

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~~(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.

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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

State of Arkansas As Engrossed: H1/23/23 S3/27/23

94th General Assembly

A Bill

Regular Session, 2023

HOUSE BILL 1102

By: Representative Pilkington

By: Senator C. Penzo

For An Act To Be Entitled

AN ACT TO CREATE THE UNIVERSAL NEWBORN SCREENING ACT;
TO ENSURE THAT NEWBORNS ARE SCREENED FOR CONDITIONS
RECOMMENDED BY THE UNITED STATES DEPARTMENT OF HEALTH
AND HUMAN SERVICES; AND FOR OTHER PURPOSES.

Subtitle

TO CREATE THE UNIVERSAL NEWBORN SCREENING
ACT; AND TO ENSURE THAT NEWBORNS ARE
SCREENED FOR CONDITIONS RECOMMENDED BY
THE UNITED STATES DEPARTMENT OF HEALTH
AND HUMAN SERVICES.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF ARKANSAS:

SECTION 1. DO NOT CODIFY. Title.

This act shall be known and may be cited as the "Universal Newborn
Screening Act".

SECTION 2. Arkansas Code § 20-15-302 is amended to read as follows:
20-15-302. Testing of newborn infants.

(a)(1)(A) There is created an advance universal newborn screening
program to be administered by the Department of Health.

(B)(i) All newborn infants shall be tested for
phenylketonuria, hypothyroidism, galactosemia, cystic fibrosis, sickle-cell
anemia, and spinal muscular atrophy core medical conditions as listed in the
recommended uniform screening panel recommended by the United States



1 Secretary of Health and Human Services, in order to provide appropriate
2 newborn screening guidelines to protect the health and welfare of newborns.

3 (ii) For each core medical condition added to the
4 list of recommended uniform screening panel by the United States Secretary of
5 Health and Human Services, the Department of Health or its designee, in
6 accordance with §20-15-304, shall begin testing for the newly added core
7 medical conditions upon approval of the appropriation of funding by the
8 General Assembly or funding under §20-15-304, if required, or within thirty-
9 six (36) months upon introduction to the recommended uniform screening panel
10 recommended by the United States Secretary of Health and Human Services.

11 ~~(B) In addition, if reliable and efficient testing~~
12 ~~techniques are available, all newborn infants shall be tested for other~~
13 ~~genetic disorders by employing procedures approved by the State Board of~~
14 ~~Health.~~

15 (2)(A) Medicaid shall reimburse the hospital that performs the
16 tests required under subdivision (a)(1) of this section for the cost of the
17 tests.

18 (B) The reimbursement shall be in addition to the
19 hospital's per diem payments for the newborn infant.

20 (b) All positive test results shall be sent immediately to
21 the Department of Health.

22 (c)(1) ~~The department~~ Department of Health shall establish and
23 maintain a program of reviewing and following up on positive cases so that
24 measures may be taken to ~~prevent intellectual and other developmental support~~
25 early diagnosis, treatment, and services for healthy development and prevent
26 disability or other permanent disabilities morbidity.

27 (2)(A) Information on newborn infants and their families
28 compiled under this section may be used by the ~~department~~ Department of
29 Health and persons or public or private entities designated by the ~~department~~
30 Department of Health.

31 (B) Information used under subdivision (c)(2)(A) of this
32 section may not refer to or disclose the identity of any person.

33 (3) All materials, data, and information received by the
34 ~~department~~ Department of Health are confidential and are not subject to
35 examination or disclosure as public information under the Freedom of
36 Information Act of 1967, § 25-19-101 et seq.

1 (d)(1) The ~~department~~ Department of Health shall conduct an intensive
2 educational and training program among physicians, hospitals, public health
3 nurses, and the public concerning the ~~disorders covered under this section~~
4 conditions.

5 (2) The program shall include information concerning:

6 (A) The nature of the ~~disorders~~ conditions;

7 (B) Testing for the detection of these ~~disorders~~
8 conditions; and

9 (C) Treatment modalities for these ~~disorders~~ conditions.

10 (e) The provisions of this section shall not apply if the parents or
11 legal guardian of a newborn infant object to the testing on medical,
12 religious, or philosophical grounds.

13 ~~(f) Testing for cystic fibrosis under this section shall be~~
14 ~~implemented only if funding is available.~~

15
16 SECTION 3. Arkansas Code § 20-15-304 is amended to read as follows:

17 20-15-304. Administration by Department of Health.

18 It shall be the duty of the Department of Health to:

19 (1) Enforce this subchapter;

20 (2) Prescribe the tests that may be administered in compliance
21 with this subchapter;

22 (3) Promulgate rules in conjunction with the Insurance
23 Commissioner establishing:

24 (A) What persons and institutions shall be required to
25 obtain specimens from newborn infants in compliance with this subchapter;

26 (B) The amount to be charged by the central laboratory for
27 processing the specimens; and

28 (C) The method of billing the charges to the persons and
29 institutions;

30 (4) Furnish copies of this subchapter and the rules promulgated
31 pursuant to this subchapter to physicians, hospitals, or other institutions
32 or persons required by its rules to have tests administered to newborn
33 infants;

34 (5)(A) Establish a central laboratory and to equip, staff, and
35 operate the laboratory for the purpose of receiving specimens from
36 physicians, hospitals, and institutions, to assure that tests are conducted,

1 and to report findings resulting from the tests.

2 (B) Initial laboratory screening tests for conditions
3 under this subchapter shall be performed by the department or its designee;

4 (6)(A) Monitor positive test results and assist in treatment and
5 care of affected infants, such follow-up procedures to begin no later than
6 ten (10) days from the time a specimen is diagnosed as positive.

7 (B) The department shall monitor infants to assure
8 appropriate testing to confirm the condition suggested by the screening test
9 results; and

10 (7) Disseminate information and advice to the public concerning
11 the dangers and effects of ~~phenylketonuria, hypothyroidism, galactosemia,~~
12 ~~sickle-cell anemia, and all other disorders of metabolism~~ conditions for
13 which screening is performed by or for the State of Arkansas.

14
15 SECTION 4. Arkansas Code § 23-79-1801(4), concerning the definition of
16 "spinal muscular atrophy" regarding coverage for newborn screening for spinal
17 muscular atrophy, is repealed.

18 ~~(4) "Spinal muscular atrophy" means a genetic disease that~~
19 ~~affects the part of the nervous system that controls voluntary muscle~~
20 ~~movement.~~

21
22 SECTION 5. Arkansas Code § 23-79-1802 is amended to read as follows:
23 23-79-1802. Coverage for newborn screening ~~for spinal muscular~~
24 ~~atrophy.~~

25 (a) A health benefit plan that is offered, issued, or renewed in this
26 state shall provide coverage for newborn screening for ~~spinal muscular~~
27 ~~atrophy~~ conditions as determined by the Department of Health under § 20-15-
28 302 by a healthcare professional on or after January 1, 2020.

29 (b) The coverage for newborn screening ~~for spinal muscular atrophy~~
30 under this section:

31 (1) Is not subject to policy deductibles or copayment
32 requirements; and

33 (2) Does not diminish or limit benefits otherwise allowable
34 under a health benefit plan.

35
36 APPROVED: 4/10/23