

APA-1  
4/18

**TRANSMITTAL SHEET FOR NOTICE OF INTENDED ACTION**

Control 420 Alabama Department of Public Health

Rule Number 420-10-1

Rule Title Care and Treatment of Infants Identified Through the Newborn Screening Program

       New XXXX Amend        Repeal        Adopt by Reference

Would the absence of the proposed rule significantly harm or endanger the public health, welfare or safety? Yes

Is there a reasonable relationship between the state's police power and the protection of the public health, safety or welfare? N/A

Is there another, less restrictive method of regulation available that could adequately protect the public? No

Does the proposed rule have the effect of directly or indirectly increasing the costs of any goods or services involved and, if so, to what degree? No

Is the increase in cost, if any, more harmful to the public than the harm that might result from the absence of the proposed rule? N/A

Are all facts of the rulemaking process designed solely for the purpose of and so they have as their primary effect, the protection of the public? Yes


Does the proposed action relate to or affect in any manner any litigation which the agency is a party to concerning the subject matter of the proposed rule? No

Does the proposed rule have an economic impact? No

If the proposed rule has an economic impact, the proposed rule is required to be accompanied by a fiscal note prepared in accordance with subsection (f) of §41-22-23, Code of Alabama, 1975.

**Certification of Authorized Official**

I certify that the attached proposed rule has been proposed in full compliance with the requirements of Chapter 22, Title 41, Code of Alabama, 1975, and that it conforms to all applicable filing requirements of the Administrative Procedure Division of the Legislative Services Agency.

Signature of Certifying Officer  Date 10/13/2021

REC'D & FILED

OCT 20 2021

LEGISLATIVE SVC AGENCY

**FORM APA2**  
**10/17**

**STATE BOARD OF HEALTH**  
**NOTICE OF INTENDED ACTION**

**AGENCY NAME:** Alabama Department of Public Health

**RULE NUMBER AND TITLE:** 420-10-1, Care and Treatment of Infants Identified Through Newborn Screening Program

**INTENDED ACTION:** To amend the current rules

**SUBSTANCE OF PROPOSED ACTION:** This amendment will allow for the Department to add new conditions to the newborn screening panel.

**TIME, PLACE, AND MANNER OF PRESENTING VIEWS:** A public hearing will be held on November 19, 2021, at 9:00 a.m., at the RSA Tower, Suite 1540, 201 Monroe Street, Montgomery, AL 36104.

**FINAL DATE FOR COMMENTS AND COMPLETION OF NOTICE:** Written or oral comments will be received until the close of the record at 5:00 p.m. on December 3, 2021. All comments and requests for copies of the proposed amendments should be addressed to the contact person listed below.

**CONTACT PERSON AT AGENCY:** Rachael Montgomery, Office of Newborn Screening Program, Department of Public Health, P.O. Box 1000, Prattville, Alabama 36067-9901, Telephone number: (334) 358-2084.



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P. Brian Hale, Agency Secretary

**ALABAMA STATE BOARD OF HEALTH  
ALABAMA DEPARTMENT OF PUBLIC HEALTH  
BUREAU OF FAMILY HEALTH SERVICES  
ADMINISTRATIVE CODE**

**CHAPTER 420-10-1  
CARE AND TREATMENT OF INFANTS IDENTIFIED  
THROUGH THE NEWBORN SCREENING PROGRAM**

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**420-10-1-.01 Purpose.**

The purpose of these rules is to provide administrative details and procedures for the care and treatment of newborns identified with phenylketonuria, hypothyroidism, galactosemia, congenital adrenal hyperplasia, hearing loss, hemoglobinopathy, biotinidase deficiency, cystic fibrosis, aminoacidopathies, fatty acid oxidation disorders, organic acidurias and acidemias, critical congenital heart disease, severe combined immunodeficiency, spinal muscular atrophy, x-linked adrenoleukodystrophy, lysosomal storage disorders, and other heritable diseases.

**Authors:** P. Scott Harris, M.D., Thomas M. Miller, M.D., Lucinda G. Ashley, R.N.-B.C., Rachael N. Montgomery, B.S.N., R.N.

**Statutory Authority:** Code of Ala. 1975, §§ 22-2-2, 22-20-3.

**History:** Filed December 21, 1987. **Amended:** Filed September 18, 2002; effective October 23, 2002. **Repealed and New Rule:** Filed December 17, 2003; effective January 21, 2004. **Amended:** Filed December 17, 2007; effective January 21, 2008. **Amended:** Filed May 17, 2013; effective June 21, 2013. **Amended:** Filed January 19, 2017; effective March 5, 2017. **Amended:** XX-XX-XXXX.

**420-10-1-.02 Definitions.**

(a) **Phenylketonuria** - A congenital disease due to a deficit in the metabolism of the amino acid phenylalanine.

(b) **Hypothyroidism** - A deficiency of thyroid gland activity with underproduction of thyroxin or the condition resulting from it.

- (c) **Hemoglobinopathy** - Any hemoglobin phenotype which is other than AA.
- (d) **Physician of Record** - The physician who requests the test.
- (e) **Galactosemia** - An inherited error in the metabolism of galactose.
- (f) **Congenital Adrenal Hyperplasia** - an inherited error in steroid biosynthesis.
- (g) **Hearing Loss** - the total or partial inability to hear sound in one or both ears.
- (h) **Biotinidase Deficiency** - inherited deficiency caused by the lack of an enzyme involved in biotin synthesis.
- (i) **Amino Acid Disorders** - inherited disorders in amino acid metabolism.
- (j) **Fatty Acid Oxidation Disorders** - inherited disorders in fatty acid metabolism.
- (k) **Organic Acid Disorders** - inherited disorders in organic acid metabolism.
- (l) **Cystic Fibrosis** - inherited disorder caused by a defective protein (cystic fibrosis transmembrane regulator) involved in the salt balance of the body.
- (m) **Critical Congenital Heart Disease (CCHD)** - a subset of congenital heart defects characterized by a diminished availability of oxygen to the body tissues that causes severe and life-threatening symptoms and requires intervention within the first days or first year of life.
- (n) **Severe Combined Immunodeficiency (SCID) and Related T-cell Lymphocyte Deficiencies** - a group of rare inherited immune disorders in which T lymphocytes are either absent or compromised.
- (o) **Licensed midwife** - a practitioner who holds a certified professional midwife credential and is licensed by the Alabama State Board of Midwifery to practice midwifery.
- (p) **Spinal Muscular Atrophy (SMA)** - a rare genetic disorder caused by spinal motor neuron gene change.
- (q) **X-Linked Adrenoleukodystrophy (X-ALD)** - a genetic disease that affects the nervous system and the adrenal glands.
- (r) **Lysosomal Storage Disorders** - inherited metabolic diseases that are characterized by an abnormal build-up of various toxic materials in the body's cells as a result of enzyme deficiencies.

**Authors:** P. Scott Harris, M.D., Thomas M. Miller, M.D., William J. Callan, Ph.D., Sharon P. Massingale, Ph.D., Aretha M. Williams, Ph.D., Lucinda G. Ashley, R.N.-B.C., Rachael N.

Montgomery, B.S.N., R.N.

**Statutory Authority:** Code of Ala. 1975, §§ 22-2-2, 22-20-3.

**History:** Filed December 21, 1987; **Amended:** Filed September 21, 1992; effective October 26, 1992. **Amended:** Filed September 18, 2002; effective October 23, 2002. **Repealed and New Rule:** Filed December 17, 2003; effective January 21, 2004. **Amended:** December 17, 2007; effective January 21, 2008. **Amended:** Filed May 17, 2013; effective June 21, 2013. **Amended:** Filed January 19, 2017; effective March 5, 2017. **Amended:** Filed July 19, 2018; effective September 2, 2018. **Amended:** XX-XX-XXXX.

#### **420-10-1-.03 Designation of Additional Heritable Diseases.**

The State Board of Health hereby designates the following as a heritable disease subject to testing, reporting, and notification requirements herein below specified.

Phenylketonuria, hypothyroidism, galactosemia, congenital adrenal hyperplasia, hearing loss, hemoglobinopathy, biotinidase deficiency, cystic fibrosis, aminoacidopathies, fatty acid oxidation disorders and organic acidurias and acidemias, CCHD, SCID, SMA, X-ALD, lysosomal storage disorders, and other heritable disorders.

**Authors:** P. Scott Harris, M.D., Thomas M. Miller, M.D., William J. Callan, Ph.D., Sharon P. Massingale, Ph.D., Aretha M. Williams, Ph.D., Lucinda G. Ashley, R.N.-B.C., Rachael N. Montgomery, B.S.N., R.N.

**Statutory Authority:** Code of Ala. 1975, §§ 22-2-2, 22-20-3.

**History:** Filed December 21, 1987; **Amended:** Filed September 21, 1992; effective October 26, 1992. **Repealed and New Rule:** Filed December 17, 2003; effective January 21, 2004.

**Amended:** December 17, 2007; effective January 21, 2008.

**Amended:** Filed May 17, 2013; effective June 21, 2013.

**Amended:** Filed January 19, 2017; effective March 5, 2017.

**Amended:** XX-XX-XXXX.

#### **420-10-1-.04 Reporting and Notification.**

(1) The Alabama Department of Public Health shall report all results of phenylketonuria, hypothyroidism, galactosemia, congenital adrenal hyperplasia, hearing loss, hemoglobinopathy, biotinidase deficiency, cystic fibrosis, aminoacidopathies, fatty acid oxidation disorders, organic acidurias and acidemias, CCHD, SCID, SMA, X-ALD, lysosomal storage disorders, and other heritable disease testing to the submitting health care provider. Test results on transferred infants may be made

available to both the transferring and receiving facilities.

(2) The submitting health care provider shall report all results, including positives, suspected positive results, and unsatisfactory specimens, to the physician of record (the physician indicated on the collection form) of the newborns tested and shall use such forms and follow such guidelines as shall be determined by the State Health Officer. The health care provider shall report the results of any hearing tests performed on the newborns to the Alabama Department of Public Health and shall use such forms and follow such guidelines as shall be determined by the State Health Officer.

(3) The Alabama Department of Public Health may release results of newborn screening tests, including hearing screening results, to any physician registered with the Secure Remote Viewer under the terms and conditions of the system without a signed release from the parent or guardian.

(4) The submitting health care provider shall screen all newborns in well baby nurseries for CCHD using pulse oximetry and shall use such forms and follow such guidelines as shall be determined by the State Health Officer.

(5) The submitting health care provider shall report the results of any failed pulse oximetry screening results to the Alabama Department of Public Health and shall use such forms and follow such guidelines as shall be determined by the State Health Officer.

(6) A licensed midwife must refer all newborns in his or her care to a licensed physician within 24 hours of age to perform Newborn Screening Tests which include: 1) bloodspot specimen tests; 2) newborn hearing screening tests; and 3) pulse oximetry screening tests. The licensed midwife must instruct the client regarding the requirements of the administration of these newborn health screening tests by the Alabama Department of Public Health.

**Authors:** P. Scott Harris, M.D., Thomas M. Miller, M.D., William J. Callan, Ph.D., Sharon P. Massingale, Ph.D., Aretha M. Williams, Ph.D., Lucinda G. Ashley, R.N.-B.C., Rachael N. Montgomery, B.S.N., R.N.

**Statutory Authority:** Code of Ala. 1975, §§ 22-2-2, 22-20-3.

**History:** Filed December 21, 1987. **Amended:** Filed September 21, 1995; effective October 26, 1992. **Amended:** Filed October 24, 1995; effective November 29, 1995. **Amended:** Filed September 18, 2002; effective October 23, 2002. **Repealed and New Rule:** Filed December 17, 2003; effective January 21, 2004. **Amended:** December

17, 2007; effective January 21, 2008. **Amended:** Filed May 17, 2013; effective June 21, 2013. **Amended:** Filed January 19, 2017; effective March 5, 2017. **Amended:** Filed July 19, 2018; effective September 2, 2018. **Amended:** XX-XX-XXXX.

**420-10-1-.05 Counseling and Management.**

(a) The Alabama Department of Public Health shall make contact with the physician of record and the parent/guardian of newborns who test positive for phenylketonuria, hypothyroidism, galactosemia, congenital adrenal hyperplasia, hearing loss, hemoglobinopathy, biotinidase deficiency, cystic fibrosis, aminoacidopathies, fatty acid oxidation disorders, organic acidurias and acidemias, CCHD, SCID, SMA, X-ALD, lysosomal storage disorders, and other heritable disorders to notify them of positive test results and ascertain whether or not these newborns are under the care of a private physician. Additionally, the Alabama Department of Public Health shall make contact with the physician of record and the parent/guardian to advise them of the services available through the Alabama Department of Public Health. Newborns who are under the care of a private physician may additionally utilize these same services. The Alabama Department of Public Health may make contact with the family to make their services available or may assist the family in obtaining the services of a private physician. Services include health assessments, treatment, and referrals to tertiary care centers.

(b) The Alabama Department of Public Health shall make contact with the submitting health care provider of newborns with failed pulse oximetry results to verify that appropriate screening, referral, and intervention services have been provided and if needed, may assist in obtaining the services. Services include health assessments, treatment, and referrals to tertiary care centers.

**Authors:** P. Scott Harris, M.D., Thomas M. Miller, M.D., William J. Callan, Ph.D., Sharon P. Massingale, Ph.D., Aretha M. Williams, Ph.D., Lucinda G. Ashley, R.N.-B.C., Rachael N. Montgomery, B.S.N., R.N.

**Statutory Authority:** Code of Ala. 1975, §§ 22-20-3.

**History:** Filed December 21, 1987. **Amended:** Filed September 21, 1992; effective October 26, 1992. **Amended:** Filed September 18, 2002; effective October 23, 2002. **Repealed and New Rule:** Filed December 17, 2003; effective January 21, 2004. **Amended:** December 17, 2007; effective January 21, 2008. **Amended:** Filed May 17, 2013; effective June 21, 2013. **Amended:** Filed January 19, 2017;

effective March 5, 2017. **Amended:** XX-XX-XXXX.

**420-10-1-.06 Fees.**

The Board shall assess and collect newborn screening fees from hospitals and birthing centers or third party payors. The newborn screening fee shall be set by the State Committee of Public Health based on the schedule of laboratory fees established by the Centers for Medicare and Medicaid Services (CMS) for use by Medicare and Medicaid. The Board shall bill the Medicaid Agency for Medicaid eligibles.

(1) Hospitals classified as "rural" by CMS or which have less than 105 beds and are located at least twenty (20) miles from the nearest acute care facility with obstetrical capabilities may have newborn screening fees waived for non-Medicaid eligible patients where there is no third party payor for such fees. The State Health Officer shall annually submit a list of hospitals to the Board which are eligible for waiver of fees.

(2) Additional reasonable and necessary fees may be charged to other payors by the hospital or physician in connection with this rule. The State Health Officer may waive fees deemed uncollectible because of a patient's inability to pay.

(3) There shall be only one (1) fee per birth collected from a hospital by the Board.

**Authors:** Lloyd Hofer, M.D., William J. Callan, Ph.D.

**Statutory Authority:** Code of Ala. 1975, §§ 22-20-3.

**History:** Filed February 19, 1992. **Amended:** Filed September 21, 1992; effective October 26, 1992. **Repealed and New Rule:** Filed December 17, 2003; effective January 21, 2004.