APA-1
11/96

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 __X__ 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?	Yes
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?	Yes

Although there are no added steps associated with the collection of blood samples, the cost to the State Lab of running a Newborn Screening (NBS) panel of tests will increase slightly by approximately $5-$25 per test. (Annual total NBS costs will increase accordingly, i.e. 60,000 births/year x $5-$25 = $300K - $1.5M.) All of these costs will be reimbursed to the State Lab by Medicaid or private insurance. None of these costs will be absorbed by the patient, their families, the hospital, or the physician.

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?	No
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 rule have an economic impact?	Yes

There will be an economic impact only as it relates to the cost of running the SCID test by the State Lab. None of these costs will be absorbed by the patient, their families, or the physician.

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 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 Reference Service.

Signature of Certifying Officer  Date 11/17/2016

APA-6
11/96

ECONOMIC IMPACT STATEMENT
FOR APA RULE
(Section 4122-23(f))

Control No. 420 Department or Agency: Public Health

Rule No.: 420-10-1

Rule Title: CARE AND TREATMENT OF INFANTS IDENTIFIED THROUGH THE NEWBORN SCREENING PROGRAM

_____ New ___X___ Amend _____ Repeal _____ Adopt by Reference

_____ This rule has no economic impact.

___X___ This rule has an economic impact, as explained below:

1. NEED/EXPECTED BENEFIT OF RULE:

The addition of severe combined immunodeficiency (SCID) to the list of mandated Newborn Screening (NBS) tests is very beneficial to the citizens of Alabama. Identifying infants with SCID can prevent infant death and reduce the state's infant mortality rate. Infants with SCID appear normal at birth but cannot fight infection. They may die before one year of age without medical treatment. If SCID is diagnosed early in life, before the onset of infection, a bone marrow transplant can successfully treat the disorder. Thus, the benefit of testing for SCID will provide an avenue for early identification and treatment for newborns.

2. COSTS/BENEFITS OF RULE AND WHY RULE IS THE MOST EFFECTIVE, EFFICIENT, AND FEASIBLE MEANS FOR ALLOCATING RESOURCES AND ACHIEVING THE STATED PURPOSE:

The desired outcome of these tests is the best possible treatment outcomes for Alabama infants afflicted with this disorder. There are no additional steps required for the SCID test. However, there will be a slight increase in the cost to the State Lab for performing the NBS panel of tests as a result of adding the SCID test to the panel. Estimates range from approximately $5 to $25 per test which would be passed on to Medicaid or private insurance companies, the cost/benefit as stated above is heavily slanted toward the benefit of Alabama's infants. There is no substitute for finding these disorders as early as possible. No costs will be absorbed by the patient, their families, or the attending physicians.

3. EFFECT OF THIS RULE ON COMPETITION:

There will be no effect on competition by the addition of the disorder to the NBS panel of screenings.

4. EFFECT OF THIS RULE ON COST-OF-LIVING AND DOING BUSINESS IN THE GEOGRAPHICAL AREA WHERE THE RULE IS TO BE IMPLEMENTED:

None

5. EFFECT OF THIS RULE ON EMPLOYMENT IN THE GEOGRAPHICAL AREA WHERE THE RULE IS TO BE IMPLEMENTED:

None

6. SOURCE OF REVENUE TO BE USED FOR IMPLEMENTING AND ENFORCING THIS RULE:

Lab fees are the source of revenue for implementing this rule change. This addition to the NBS panel of tests will incur approximately $5-$25 per test which will be charged to Medicaid or private insurance to reimburse the State Lab for the cost of running the new tests. No costs will be absorbed by the patient, their families, or the attending physicians.

7. THE SHORT-TERM/LONG-TERM ECONOMIC IMPACT OF THIS RULE ON AFFECTED PERSONS, INCLUDING ANALYSIS OF PERSONS WHO WILL BEAR THE COSTS AND THOSE WHO WILL BENEFIT FROM THE RULE:

This rule change will benefit the families of Alabama. What small impact the increased cost of testing might have is more than made up for by the enormously reduced costs of early identification and treatment of the patients. There are no additional steps required on the part of the hospital or the physician.

8. UNCERTAINTIES ASSOCIATED WITH THE ESTIMATED BENEFITS AND BURDENS OF THE RULE, INCLUDING ANALYSIS OF PERSONS WHO WILL BEAR THE COSTS AND THOSE WHO WILL BENEFIT FROM THE RULE:

None

9. THE EFFECT OF THIS RULE ON THE ENVIRONMENT AND PUBLIC HEALTH:

The adoption of this rule will have an enormously positive effect on the public health of Alabama. This will be seen in the early identification of infants with SCID and a decrease in infant deaths as a result of SCID.

10. DETRIMENTAL EFFECT ON THE ENVIROMENT AND PUBLIC HEALTH IF THE RULE IS NOT IMPLEMENTED:

None

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

TABLE OF CONTENTS

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, and other heritable diseases.

Authors: Thomas M. Miller, M.D., Lucinda G. Ashley, R.N.-B.C.

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.

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, CFTR) 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.

Authors: Thomas M. Miller, M.D., William J. Callan, Ph.D., Lucinda G. Ashley, R.N.-B.C.

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.

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 and other heritable disorders.

Authors: Thomas M. Miller M.D., William J. Callan, Ph.D., Lucinda G. Ashley, R.N.-B.C.

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.

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, 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 ~~Alabama Voice Response System~~ 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.

Authors: Thomas M. Miller, M.D., William J. Callan, Ph.D., Lucinda G. Ashley, R.N.-B.C.

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.

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, 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: Thomas M. Miller, M.D., William J. Callan, Ph.D., Lucinda G. Ashley, R.N.-B.C.
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.

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.