

APA-1
4/18

TRANSMITTAL SHEET FOR NOTICE OF INTENDED ACTION

Control 420 Alabama Department of Public Health

Rule Number 420-10-1-.04

Rule Title Reporting and Notification

 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? 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? 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 Service Agency.

Signature of Certifying Officer *P. Buntale* Date 5/15/18

REC'D & FILED

MAY 18 2018

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-.04, Reporting and Notification

INTENDED ACTION: To amend the current rules

SUBSTANCE OF PROPOSED ACTION: This amendment will allow for the Department to require a licensed midwife to refer all newborns in his or her care to a licensed physician within 24 hours of age to perform Newborn Screening Tests.

TIME, PLACE, AND MANNER OF PRESENTING VIEWS: A public hearing will be held on June 21, 2018, 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 Thursday, July 5, 2018. 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, Newborn Screening Program, Department of Public Health, P.O. Box 303017, Montgomery, Alabama 36130-3017, Telephone number: (334) 206-5955.



P. Brian Hale, Agency Secretary

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 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: Thomas M. Miller, M.D., William J. Callan, 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 May 18, 2018; effective
XX-XX-XXXX.