REQUEST FOR TECHNICAL CHANGE

AGENCY: Commission for Public Health

RULE CITATION: 10A NCAC 42B .0102

DEADLINE FOR RECEIPT: Tuesday, September 8, 2020

***PLEASE NOTE:* This request may extend to several pages. Please be sure you have reached the end of the document.**

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may call our office to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following technical changes be made:

In (a), what is "this laboratory"? Is this the State laboratory? A lab at a hospital? Please clarify. I assume it's the latter, but that's not clear here.

Overall, what is the intent of (b)? I'm concerned with ambiguity and clarity in this Paragraph.

In (b), is the screening fee not established by .0108?

In (b), delete or define "adequate"

How are "assurances" made that the lab meets all requirements?

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Amber May
Commission Counsel
Date submitted to agency: August 24, 2020

10A NCAC 42B .0102 is amended as published in 34:23 NCR 2176–2177 as follows:

10A NCAC 42B .0102 ~~CLINICAL CHEMISTRY/NEWBORN~~ NEWBORN SCREENING

(a) This laboratory will conduct screening for ~~examine specimens for evidence of certain inborn errors of metabolism, for the detection of chronic diseases, diabetes, renal diseases, hypertension, certain clinical chemistry and hematology tests when requested by authorized senders of specimens within the guidelines of the Division of Maternal and Child Health and the Division of Public Health.~~ the core conditions listed on the Recommended Uniform Screening Panel developed by the Secretary of the United States Department of Health and Human Services and the Advisory Committee on Heritable Disorders of Newborns and Children (the "RUSP"), which is hereby incorporated by reference, including any subsequent editions and amendments, and available free of charge at https://www.hrsa.gov/advisory-committees/heritable-disorders/rusp/index.html. Specimens shall be submitted to this laboratory for screening in accordance with the procedures set forth in 10A NCAC 43H .0314.

(b) ~~This laboratory performs tests for hemoglobinopathies such as sickle cell trait and disease.~~ The process to develop and implement new screening for the conditions described in Paragraph (a) of this Rule shall begin after the screening fee is established and adequate funds exist to acquire instrumentation, equipment, Program supplies, Program personnel, perform assay validations, implement preventative follow-up interventions, secure necessary infrastructure, and with the assurance that the laboratory has met all federal, State, and local requirements.

History Note: *Authority G.S. 130A-88; 130A-125;*
Eff. October 1, 1985;
Amended Eff. September 1, 1990;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 23, 2017; ~~2017.~~
Amended Eff. January 1, 2021.

10A NCAC 42B .0108 is adopted as published in 34:23 NCR 2176–2177 as follows:

10A NCAC 42B .0108 FEES

(a) The State Laboratory of Public Health shall charge a fee of one hundred thirty-two dollars ($132.00) to cover the programmatic costs of the newborn screening performed by the State Laboratory of Public Health under 10A NCAC 42B .0102(a).

(b) In accordance with G.S. 130A-125, the Commission for Public Health, in consultation with the Secretary of the North Carolina Department of Health and Human Services, has determined that the fee listed in Paragraph (a) of this Rule is necessary to offset the cost of incorporating the conditions identified in 10A NCAC 42B .0102(a) in the Newborn Screening Program.

History Note: Authority G.S. 130A-125;
Eff. January 1, 2021.

REQUEST FOR TECHNICAL CHANGE

AGENCY: Commission for Public Health

RULE CITATION: 10A NCAC 43H .0314

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The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may call our office to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following technical changes be made:

> *In (a), I'm not sure that a change is needed here, but how is the attending physician to "ensure the collection"?*

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Amber May
Commission Counsel
Date submitted to agency: August 24, 2020

10A NCAC 43H .0314 is amended with changes as published in 34:23 NCR 2176–2177 as follows:

10A NCAC 43H .0314 SUBMISSION OF BLOOD SPECIMENS FOR SCREENING OF NEWBORNS

(a) The attending physician shall ~~draw~~ collect or ensure the collection of a blood specimen for each infant born in North Carolina and shall submit such specimens to the North Carolina State Laboratory of ~~for~~ Public Health for testing as set forth in 10A NCAC 42B .0102. ~~for the following metabolic and other hereditary and congenital disorders:~~

~~(1) phenylketonuria (PKU);~~

~~(2) galactosemia;~~

~~(3) congenital primary hypothyroidism;~~

~~(4) congenital adrenal hyperplasia (21-hydroxylase deficiency); and~~

~~(5) sickle cell disease.~~

(b) Notwithstanding Paragraph (a) of this Rule, parents or guardians may object to screening in accordance with G.S. 130A-125(b).

(c) The hearing screening component of the Department's Newborn Screening Program is found in 10A NCAC 43F .1200.

History Note: *Authority G.S. 130A-125;*
Eff. April 1, 1992;
Transferred and Recodified from 15A NCAC 21E .0501 Eff. February 10, 1993;
Amended Eff. April 1, 1994;
Temporary Amendment Eff. October 1, 1999;
Amended Eff. August 1, 2000;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 6, 2016; ~~2016.~~
Amended Eff. January 1, 2021.