



NC DEPARTMENT OF
**HEALTH AND
HUMAN SERVICES**

Commission for Public Health

ROY COOPER • Governor
MANDY COHEN, MD, MPH • Secretary
MARK T. BENTON • Assistant Secretary for Public Health
Division of Public Health

MEMORANDUM

DATE: June 1, 2020

TO: Rulemaking Interested Persons

FROM: Virginia Niehaus, Rulemaking Coordinator, Commission for Public Health and Director of Regulatory and Legal Affairs, Division of Public Health

RE: Notification of Proposed Rule Actions: 10A NCAC 42B .0102, .0108 and 10A NCAC 43H .0314 – Newborn Screening

Pursuant to G.S. 150B-21.2, this memorandum serves as the required notice to interested persons that the North Carolina Commission for Public Health (CPH) is proposing to amend Rules 10A NCAC 42B .0102 and 43H .0314 and to adopt Rule 10A NCAC 42B .0108. G.S. 130A-125 directs CPH to amend its rules to ensure that each condition 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) is included in the Newborn Screening Program. It also permits CPH, in consultation with the Secretary of the NC Department of Health and Human Services, to increase the fee for newborn screening by no more than the amount necessary to offset the cost of incorporating a condition listed on the RUSP. The proposed rules align the Newborn Screening Program with the RUSP and increase the newborn screening fee by four dollars to offset the cost of incorporating Spinal Muscular Atrophy (SMA). CPH has submitted notice of its intent to make these rule changes to the NC Office of Administrative Hearings (OAH).

In accordance with G.S. 150B-21.4, a fiscal note was prepared for these proposed rules and approved by CPH. The changes will have an impact on state funds as well as a substantial economic impact. The fiscal note was approved by the NC Office of State Budget and Management (OSBM) on April 22, 2020.

The notice of text that was published in today's edition of the NC Register is attached to this memorandum and may be found on OAH's website at <https://www.oah.nc.gov/documents/nc-register>. The text of the proposed rules and the fiscal note may be found on CPH's website at <https://cph.publichealth.nc.gov/>.

A public hearing on these rules is scheduled for Friday, June 26, 2020 at 10:00 am. In an abundance of caution and to address protective measures to help prevent the spread of COVID-19, the public hearing will be held by teleconference. You may participate in the public hearing by dialing 919-715-0769 (no access code).

CPH is accepting public comments on the proposed rules and fiscal note from June 1, 2020 to July 31, 2020. You may submit comments by email to cphcomment@lists.ncmail.net or by mail to Virginia Niehaus, Rulemaking Coordinator, Commission for Public Health, 1931 Mail Service Center, Raleigh, NC 27699-1931. Comments will also be accepted at the public hearing. The proposed effective date of these rules is October 1, 2020.

NC DEPARTMENT OF HEALTH AND HUMAN SERVICES • DIVISION OF PUBLIC HEALTH

LOCATION: 5605 Six Forks Road, Building 3, Raleigh, NC 27609

MAILING ADDRESS: 1931 Mail Service Center, Raleigh, NC 27699-1931

www.ncdhhs.gov • TEL: 919-707-5000 • FAX: 919-870-4829

AN EQUAL OPPORTUNITY / AFFIRMATIVE ACTION EMPLOYER

Should you have questions related to this memorandum, the proposed rules, or the fiscal note, please contact Dee Pettit, Assistant Director, State Laboratory of Public Health, Division of Public Health, at 919-807-8940.

Attachment

cc: Dr. Ron May, Chair, Commission for Public Health
Mr. Mark Benton, Assistant Secretary, Division of Public Health
Dr. Scott Shone, Director, State Laboratory of Public Health, Division of Public Health
Dr. Dee Pettit, Assistant Director, State Laboratory of Public Health, Division of Public Health
Ms. Kirsten Leloudis, Program Manager, Regulatory and Legal Affairs, Division of Public Health

TITLE 10A – DEPARTMENT OF HEALTH AND HUMAN SERVICES

Notice is hereby given in accordance with G.S. 150B-21.2 that the Commission for Public Health intends to adopt the rule cited as 10A NCAC 42B .0108 and amend the rules cited as 10A NCAC 42B .0102 and 43H .0314.

Link to agency website pursuant to G.S. 150B-19.1(c): <https://cph.publichealth.nc.gov/>

Proposed Effective Date: October 1, 2020

Public Hearing:

Date: June 26, 2020

Time: 10:00 a.m.

Location: In an abundance of caution and to address protective measures to help prevent the spread of COVID-19, this public hearing will be held by teleconference at 919-715-0769 (no access code).

Reason for Proposed Action: N.C.G.S. 130A-125 directs the Commission for Public Health (CPH) to amend its rules to ensure that each condition 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) is included in the Newborn Screening Program. It also permits CPH, in consultation with the Secretary of the NC Department of Health and Human Services, to increase the fee for newborn screening by no more than the amount necessary to offset the cost of incorporating a condition listed on the RUSP. The proposed rules align the Newborn Screening Program with the RUSP and increase the newborn screening fee by four dollars to offset the cost of incorporating Spinal Muscular Atrophy (SMA).

Comments may be submitted to: Virginia Niehaus, CPH Rulemaking Coordinator, 1931 Mail Service Center, Raleigh, NC 27699-1931; email cphcomment@lists.ncmail.net

Comment period ends: July 31, 2020

Procedure for Subjecting a Proposed Rule to Legislative Review: If an objection is not resolved prior to the adoption of the rule, a person may also submit written objections to the Rules Review Commission after the adoption of the Rule. If the Rules Review Commission receives written and signed objections after the adoption of the Rule in accordance with G.S. 150B-21.3(b2) from 10 or more persons clearly requesting review by the legislature and the Rules Review Commission approves the rule, the rule will become effective as provided in G.S. 150B-21.3(b1). The Commission will receive written objections until 5:00 p.m. on the day following the day the Commission approves the rule. The Commission will receive those objections by mail, delivery service, hand delivery, or facsimile transmission. If you have any further questions concerning the submission of objections to the Commission, please call a Commission staff attorney at 919-431-3000.

Fiscal impact. Does any rule or combination of rules in this notice create an economic impact? Check all that apply.

- State funds affected
- Local funds affected
- Substantial economic impact (>= \$1,000,000)
- Approved by OSBM
- No fiscal note required

CHAPTER 42 - LABORATORY SERVICES

SUBCHAPTER 42B - LABORATORY SECTIONS

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.

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.

SUBCHAPTER 43H - SICKLE CELL SYNDROME: GENETIC COUNSELING:

SECTION .0300 - GENETIC HEALTH CARE

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

(a) The attending physician shall draw collect 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.