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: May 28, 2021

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 Permanent Rule Adoption: 10A NCAC 41A .0107

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 permanently adopt rule 10A NCAC 41A .0107 to require healthcare providers and laboratories to report all COVID-19 diagnostic test results, both positive and negative, to public health officials. This rule was previously adopted under emergency and temporary rulemaking. However, this permanent adoption is needed to ensure that these reporting requirements do not expire from the administrative code. CPH has submitted notice of its intent to adopt this rule to the NC Office of Administrative Hearings (OAH).

In accordance with G.S. 150B-21.4, a fiscal note was prepared for the proposed rule and approved by CPH. The proposed rule is expected to have an impact on state funds and the private sector, which in aggregate is estimated to constitute a substantial economic impact. The proposed rule is expected to have little to no impact on local government. The fiscal note was approved by the NC Office of State Budget and Management (OSBM) on April 20, 2021.

The notice of text that will be published in the NC Register on June 1, 2021 is attached to this memorandum and may be found on or after June 1, 2021 at OAH's website at https://www.oah.nc.gov/documents/nc-register. The text of the proposed rule and fiscal note may be found on the CPH's website at https://cph.publichealth.nc.gov/.

A public hearing on the rule is scheduled for Monday, June 28, 2021 at 2:00 pm. The public hearing will be held by teleconference. You may participate in the public hearing by dialing 919-715-0769. No access code is required.

CPH is accepting public comments on the proposed rule and fiscal note from June 1, 2021 through August 2, 2021. 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 this rule is October 1, 2021.

Should you have questions related to this memorandum, the proposed rule, or the fiscal note, please contact Dr. Zack Moore, Epidemiology Section Chief, Division of Public Health at 919-546-1725.

Attachment

cc:
Dr. Ronald May, Chair, Commission for Public Health
Mr. Mark Benton, Assistant Secretary for Public Health, Division of Public Health
Dr. Zack Moore, Section Chief, Epidemiology, Division of Public Health
Dr. Jean-Marie Maillard, Medical Director, Communicable Disease Branch, 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 41A .0107.*

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

Proposed Effective Date: *October 1, 2021*

Public Hearing:
Date: *June 28, 2021*
Time: *2:00 p.m.*
Location: *This public hearing will be held by teleconference at (919) 715-0769 (no access code).*

Reason for Proposed Action: *COVID-19, a novel coronavirus, was identified as the cause of an emerging infectious disease outbreak in December 2019 in Wuhan, Hubei Province, China. This novel coronavirus causes respiratory illness ranging in severity from mild illness to death. The North Carolina Division of Public Health is working closely with the Centers for Disease Control and Prevention (CDC) to monitor and respond to this pandemic in North Carolina.*

Due to the widespread community transmission of this serious, infectious disease, testing is occurring in non-traditional environments, such as community-based testing sites. For this reason, reporting requirements need to be extended to other types of healthcare providers potentially involved in testing, such as nurses, pharmacists, and dentists. It is also imperative that public health officials receive not only positive tests results, but also negative test results, to better understand the prevalence of the disease in North Carolina.

To address this, the legislature enacted S.L. 2020-4 Sec. 4.10(a)(1) and the State Health Director issued a temporary order, pursuant to her authority under G.S. 130A-141.1, requiring healthcare providers and laboratories to report all COVID-19 diagnostic test results, both positive and negative, effective July 7, 2020. On September 15, 2020, the Commission for Public Health (CPH) adopted 10A NCAC 41A .0107 under emergency procedures and simultaneously proposed to adopt 10A NCAC 41A .0107 under temporary procedures to continue the reporting requirement. The temporary rule was adopted by CPH at its meeting on November 4, 2020. This proposed permanent rule would ensure the continuation of the requirement that healthcare providers and laboratories report all COVID-19 diagnostic test results, both positive and negative, to public health officials.

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: *August 2, 2021*

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 41 - EPIDEMIOLOGY HEALTH

SUBCHAPTER 41A - COMMUNICABLE DISEASE CONTROL

SECTION .0100 - COMMUNICABLE DISEASE CONTROL

10A NCAC 41A .0107 REPORTING OF COVID-19 DIAGNOSTIC TEST RESULTS

(a) For purposes of this Rule, the following definitions shall apply:

(1) "COVID-19 diagnostic test" means any nucleic acid or antigen test that identifies SARS-CoV-2, the virus that causes COVID-19.

(2) "Electronic laboratory reporting" means the automated messaging of laboratory reports sent to the Division of Public Health using a machine-readable electronic communication protocol.

(3) "Healthcare provider" means a healthcare provider as defined in G.S. 130A-476(g).

(4) "Laboratory" means a facility that performs testing on specimens obtained from humans for the purpose of providing information for health assessment and for the diagnosis, prevention, or treatment of disease and is certified by the United States Department of Health and Human Services under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) and implementing regulations. This definition includes a healthcare provider who performs testing in an on-site facility that meets these requirements.

(b) Each person in charge of a laboratory providing diagnostic service in this State shall report the results of all COVID-19 diagnostic tests to the Division of Public Health using electronic laboratory reporting. For purposes of COVID-19, a novel coronavirus under Rule .0101(c)(1) of this Section, the required method of reporting set out in Rules .0101(c) and .0102(d)(3) of this Section shall not apply. The report shall include all of the elements required to be reported under the United States Department of Health and Human Services, laboratory data reporting guidance, which is hereby incorporated by reference, including any subsequent amendments and editions, and available free of charge at https://www.hhs.gov/sites/default/files/covid-19-laboratory-data-reporting-guidance.pdf.

(c) The requirements set forth in Paragraph (b) of this Rule shall be considered met if a laboratory:

(1) submits a COVID-19 Laboratory Data Automation Registration form to the Division of Public Health and acts to onboard to electronic laboratory reporting. This form shall be submitted within seven calendar days of the date the laboratory starts performing COVID-19 diagnostic testing and shall contain the following elements:

(A) the name, address, phone number, and CLIA number of the laboratory;

(B) the name, address, and phone number of the person in charge of the laboratory or that person's designee;

(C) the type of test performed, testing capacity, and whether the laboratory will use a third-party laboratory to perform part or all of the testing; and

(D) if the laboratory will use a third-party laboratory to perform part or all of the testing, the information in Parts (A)-(B) of this Subparagraph for the third-party laboratory; and

(2) until onboarding to electronic laboratory reporting is complete:

(A) reports the results of positive COVID-19 diagnostic tests to the Division of Public Health, including all elements required in Paragraph (b) of this Rule, by telefax; and

(B) reports the aggregate number of positive and negative nucleic acid COVID-19 diagnostic tests and the aggregate number of positive and negative antigen COVID-19 diagnostic tests per day to the Division of Public Health through an online survey available at: https://files.nc.gov/covid/documents/eCATR-Reference-Guide.pdf.

(d) The requirements set forth in Paragraph (b) of this Rule shall be considered met if a laboratory that completes fewer than 50 total COVID-19 diagnostic tests per week submits results as set out in Subparagraph (c)(2) of this Rule.

(e) Healthcare providers who order COVID-19 diagnostic testing in this State shall:

(1) report the results of positive COVID-19 diagnostic tests by telefax to the local health director in the county or district where the patient resides. The report shall contain:

(A) patient first and last name, date of birth, address, county of residence, phone number, sex, race, and ethnicity;

(B) provider name, address, phone number, and NPI;

(C) the specimen collection date, the test order date, and the test result date;

(D) the test result; and

(E) all other available elements required in Paragraph (b) of this Rule; and

(2) report the aggregate number of positive and negative nucleic acid COVID-19 diagnostic tests and the aggregate number of positive and negative antigen COVID-19 diagnostic tests per day to the Division of Public Health through an online survey.

(f) The requirements set forth in Paragraph (e) of this Rule shall be considered met if a healthcare provider:

(1) verifies that the laboratory that receives the specimen for testing will report the test result in accordance with Paragraph (b) of this Rule; and

(2) includes patient first and last name, date of birth, address, county of residence, phone number, sex, race, ethnicity, and specimen collection date on the lab order.

(g) The requirement for healthcare providers to report COVID-19 diagnostic test results, as set out in Paragraph (e) of this Rule, is separate from the requirement for physicians to report suspected infections of COVID-19, a novel coronavirus, including positive COVID-19 diagnostic test results, in accordance with G.S. 130A-135 and Rules .0101(a) and .0102(a) of this Section.

(h) Laboratories and healthcare providers who are required to report under this Rule shall report positive COVID-19 diagnostic test results immediately upon receiving the result and negative COVID-19 diagnostic test results within 24 hours of receiving the result. Results reported to a local health department under this Rule shall be forwarded to the Division of Public Health within 24 hours of receipt by the local health department.

History Note: *Authority G.S. 130A-134; 130A-135; 130A-139; 130A-141; 130A-141.1; S.L. 2020-4, s. 4.10(a)(1); P.L. 100-578; 42 C.F.R. 493;*
Emergency Adoption Eff. September 25, 2020;
Temporary Adoption Eff. December 1, 2020.