



NC DEPARTMENT OF  
**HEALTH AND  
HUMAN SERVICES**

**Commission for Public Health**

**ROY COOPER** • Governor

**KODY H. KINSLEY** • Secretary

**MARK T. BENTON** • Deputy Secretary for Health

**SUSAN KANSAGRA, MD, MBA** • Assistant Secretary for Public Health, Division of Public Health

**MEMORANDUM**

**DATE:** June 1, 2022

**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 Amendment: 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 amend rule 10A NCAC 41A .0107. This rule governs the reporting of COVID-19 diagnostic test results by laboratories and healthcare providers to public health officials. Since the permanent adoption of this rule, the COVID-19 pandemic has continued to evolve. This rule is proposed for amendment to align reporting requirements with recent updates to federal guidance and current best practices. 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 the proposed rule and approved by CPH. The proposed rule is not expected to have an impact on state or local funds. It is expected to have an impact on the private sector, but not rising to the level of a substantial economic impact. The fiscal note was approved by the NC Office of State Budget and Management (OSBM) on April 18, 2022.

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/rules-division/north-carolina-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 proposed rule is scheduled for Monday, July 11, 2022 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 from June 1, 2022 through August 1, 2022. You may submit comments by email to [cphcomment@lists.ncmail.net](mailto: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, 2022.

Should you have questions related to this memorandum, the proposed rule, please contact Dr. Carl Williams, North Carolina Department of Health and Human Services, Division of Public Health, Communicable Disease Branch at (919) 546-1660.

**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

Attachment

cc:

Dr. Ronald May, Chair, Commission for Public Health

Dr. Susan Kansagra, Assistant Secretary for Public Health, Division of Public Health

Dr. Zack Moore, Epidemiology Section Chief, Division of Public Health

Ms. Evelyn Foust, Communicable Disease Branch, Epidemiology Section, Division of Public Health

Dr. Carl Williams, Communicable Disease Branch, Epidemiology Section, Division of Public Health

Ms. Kirsten Leloudis, Office of 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 amend 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, 2022*

**Public Hearing:**

**Date:** *July 11, 2022*

**Time:** *2:00 p.m.*

**Location:** *This public hearing will be held by teleconference at (919) 715-0769 (no access code required).*

**Reason for Proposed Action:** *10A NCAC 41A .0107 governs the reporting of COVID-19 diagnostic test results by laboratories and healthcare providers to public health officials. Since the permanent adoption of this rule, the COVID-19 pandemic has continued to evolve. This rule is proposed for amendment to align reporting requirements with recent updates to federal guidance and current best practices.*

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

**Comment period ends:** *August 1, 2022*

**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 984-236-1850.

**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 ( $\geq$  \$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)(1).
- (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) at P.L. 100-578 and implementing regulations at 42 C.F.R. 493, which are hereby incorporated by reference, including any subsequent amendments or editions, and available free of charge at <https://www.congress.gov/public-laws/> and <http://ecfr.gov/>, respectively. 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~~ Reports shall be made in alignment with the requirements for laboratories by entity and type of testing and minimum data elements as set forth in ~~shall include all of the elements required to be reported under~~ the United States Department of Health and Human Services, Services' COVID-19 Pandemic Response, Laboratory Data Reporting: CARES Act Section 18115 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, ~~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 telefacsimile, telefaecsimile; 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://covid19.ncdhhs.gov/media/2889/open>.~~

(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 telefacsimile 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 available at: <https://covid19.ncdhhs.gov/media/2889/open>.~~

~~(f) The requirements set forth in Paragraph (c) 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 (c) 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)(c)~~ Laboratories and healthcare providers who that 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, as applicable, 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);  
Emergency Adoption Eff. September 25, 2020;  
Temporary Adoption Eff. December 1, 2020;  
Eff. October 1, 2021.*