REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: Commission for Public Health

RULE CITATION: 10A NCAC 41A .0107

DEADLINE FOR RECEIPT: Friday, September 9, 2022.

***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 email the reviewing attorney to inquire concerning the staff recommendation.

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

In (b), line 21, what do you mean by "Reports shall be made in alignment with…"? Are you requiring something other than compliance with the reporting requirements in the US DHHS document you incorporate by reference?

In (e), p.2, line 36-37, under what authority are you requiring reporting of negative tests? G.S. 130A-139(4) speaks to positive tests only. Is there another statute you're relying on here?

In (e), line 37, what do you mean by "as applicable" with respect to reporting of negative tests? Please clarify.

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

Brian Liebman
Commission Counsel
Date submitted to agency: September 2, 2022

10A NCAC 41A .0107 is amended as published in 36:23 NCR 1822-1823 as follows:

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. ~~telefaesimile; 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 telefascimile 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 (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)~~(e) 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; ~~2021.~~
Amended Eff. October 1, 2022.