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: September 15, 2020

TO: Interested Parties

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

RE: Notification of Emergency and Proposed Temporary Rule Actions: 10A NCAC 41A .0107

The Commission for Public Health (CPH) has adopted 10A NCAC 41A .0107 under emergency procedures and simultaneously proposed to adopt 10A NCAC 41A .0107 under temporary procedures. G.S. § 150B-21.1 requires a rulemaking body to notify certain individuals of its intent to adopt temporary rules and the date, time, and location of the public hearing on the rules.

These rules require healthcare providers and laboratories to report all COVID-19 diagnostic test results, both positive and negative, to public health officials. 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. As of September 13, 2020, over 28,600,000 confirmed cases and 900,000 deaths had been reported from 216 countries, including the United States. The first U.S. case was reported in a traveler returning from Wuhan on January 21, 2020 in Washington State. As of September 13, over 6,400,000 cases and 190,000 deaths had been reported in the U.S., and over 180,000 cases and 3,000 deaths had been reported in North Carolina. 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. An emergency rule was adopted on September 15, 2020 to continue these reporting requirements by rule while temporary and eventually permanent rules are pursued. Immediate adoption is required due to the serious and unforeseen threat posed by this infectious disease.

The public hearing on the temporary rule is scheduled for Friday, October 9, 2020 at 10:00 a.m. by teleconference at (919) 715-0769 (no access code).

CPH is accepting public comments on the temporary rule from September 15, 2020 – October 16, 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 emergency rule and proposed temporary rule are attached to this memorandum and available at https://cph.publichealth.nc.gov/.

If you have technical questions related to this memorandum or the rules, please contact Dr. Zack Moore, Epidemiology Section Chief, Division of Public Health at (919) 546-1725.

cc: Dr. Ronald May, Chair, Commission for Public Health
Mr. Mark Benton, Assistant Secretary, Division of Public Health
Dr. Zack Moore, Epidemiology Section Chief, Division of Public Health
Ms. Kirsten Leloudis, Program Manager, Regulatory and Legal Affairs, Division of Public Health

10A NCAC 41A .0107 is adopted under emergency procedures 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).

(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 in good faith 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 Subparagraphs (c)(1)(A)-(B) 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 secure 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.

(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 secure 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 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, Sec. 4.10(a)(1); P.L. 100-578; 42 C.F.R. 493;*
Emergency Adoption Eff. September 25, 2020.

10A NCAC 41A .0107 is proposed for adoption under temporary procedures 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).

(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 in good faith 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 Subparagraphs (c)(1)(A)-(B) 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 secure 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.

(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 secure 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 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, Sec. 4.10(a)(1); P.L. 100-578; 42 C.F.R. 493;*