TEMPORARY RULE-MAKING FINDINGS OF NEED

[Authority G.S. 150B-21.1]

OAH USE ONLY
VOLUME:
ISSUE:

1. Rule-Making Agency: NC Commission for Public Health

2. Rule citation & name: 10A NCAC 41A .0107, Reporting of COVID-19 Diagnostic Test Results

3. Action: ☒ **Adoption** ☐ **Amendment** ☐ **Repeal**

4. Was this an Emergency Rule: ☒ **Yes** ☐ **No** **Effective date: 9/25/2020**

5. Provide dates for the following actions as applicable:

a. Proposed Temporary Rule submitted to OAH: 9/15/2020

b. Proposed Temporary Rule published on the OAH website: 9/22/2020

c. Public Hearing date: 10/9/2020

d. Comment Period: 9/15/2020 – 10/16/2020

e. Notice pursuant to G.S. 150B-21.1(a3)(2): 9/15/2020

f. Adoption by agency on: 11/4/2020

g. Proposed effective date of temporary rule [if other than effective date established by G.S. 150B- 21.1(b) and G.S. 150B-21.3]:

h. Rule approved by RRC as a permanent rule [See G.S. 150B-21.3(b2)]:

6. Reason for Temporary Action. Attach a copy of any cited law, regulation, or document necessary for the review.

☒ **A serious and unforeseen threat to the public health, safety or welfare.**

☒ **The effective date of a recent act of the General Assembly or of the U.S. Congress.**
Cite: SL 2020-4
Effective date:

☐ **A recent change in federal or state budgetary policy.**
Effective date of change:

☐ **A recent federal regulation.**
Cite:
Effective date:

☐ **A recent court order.**
Cite order:

☐ **State Medical Facilities Plan.**

☐ **Other:**

Explain: 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 November 3, 2020, over 46,800,000 confirmed cases and 1,200,000 deaths had been reported from 219 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 November 3, over 9,200,000 cases and 230,000 deaths had been reported in the U.S., and over 280,000 cases and 4,000 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. This temporary rule is needed to continue these reporting requirements while a permanent rule is pursued. Adoption of this temporary rule is required due to the serious and unforeseen threat to public health posed by this infectious disease.

7. Why is adherence to notice and hearing requirements contrary to the public interest and the immediate adoption of the rule is required?

This meets temporary rule criteria under G.S.150B-21.1(a) because adherence to the notice and hearing requirements would be contrary to the public interest and immediate adoption of the rule is required due to the serious and unforeseen threat posed by this infectious disease to the public health or safety.

8. Rule establishes or increases a fee? (See G.S. 12-3.1)

☐ **Yes**
Agency submitted request for consultation on:
Consultation not required. Cite authority:

☒ **No**

9. Rule-making Coordinator: Virginia Niehaus

Phone: (919) 634-0184

E-Mail: virginia.niehaus@dhhs.nc.gov

Agency contact, if any: Kirsten Leloudis

Phone: (919) 607-0813

E-Mail: kirsten.leloudis@dhhs.nc.gov

10. Signature of Agency Head*:

11.4.2020

*** If this function has been delegated (reassigned) pursuant to G.S. 143B-10(a), submit a copy of the delegation with this form.**

Typed Name: Dr. Ron May

Title: Chair, NC Commission for Public Health

E-Mail: RMay@carolinaeasthealth.com

RULES REVIEW COMMISSION USE ONLY	
Action taken: ☐ Date returned to agency:	Submitted for RRC Review:

10A NCAC 41A .0107 is adopted with changes 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.~~] 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 [~~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 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, Sec. 4.10(a)(1); P.L. 100-578; 42 C.F.R. 493;*
Emergency Adoption Eff. September 25, [~~2020.~~]2020;
Temporary Adoption Eff. December 1, 2020.

10A NCAC 41A .0212 is amended with changes under temporary procedures as follows:

10A NCAC 41A .0212 HANDLING AND TRANSPORTATION OF BODIES

(a) Persons handling the body of any person who has died shall comply with the standard precautions for all patient care published by the United States Centers for Disease Control and Prevention, which are hereby incorporated by reference, including any subsequent amendments and editions, and available free of charge at: https://www.cdc.gov/infectioncontrol/basics/standard-precautions.html.

~~(a)~~(b) It shall be the duty of the ~~physician~~ physician, physician assistant, or nurse practitioner attending to any person who dies and is known to be infected with HIV, plague, ~~or~~ hepatitis ~~B~~ B, or COVID-19 or any person who dies and is known or reasonably suspected to be infected with smallpox, rabies, severe acute respiratory syndrome (SARS), or Jakob-Creutzfeldt to provide ~~written~~ written, verbal, or electronic notification to ~~all~~ individuals handling the body of the proper precautions to prevent ~~infection.~~ infection, as set forth in Paragraphs (d), (e), and (f) of this Rule. This ~~written~~ written, verbal, or electronic notification shall be provided to the funeral service director, funeral service worker, or body transporter ~~personnel~~ at the time the body is removed from any hospital, nursing home, or other health care facility. When the patient dies in a location other than a health care facility, the ~~attending physician~~ physician, physician assistant, or nurse practitioner shall notify the funeral service director, funeral service worker, or body transporter ~~personnel~~ ~~verbally~~ of the precautions required as soon as the ~~physician~~ physician, physician assistant, or nurse practitioner becomes aware of the death. These precautions are noted in Paragraphs ~~(b)~~(d), (e), and ~~(c).~~(f) of this Rule. The duty to notify shall be considered met if performed by one of the following individuals:

(1) the physician, physician assistant, or nurse practitioner attending to the person who [~~died~~]died; or

(2) a designated representative of the physician, physician assistant, or nurse practitioner.

(c) It shall also be the duty of a medical examiner with jurisdiction pursuant to G.S. 130A-383 over the body of any person who dies and is known to be infected with COVID-19 to provide written, verbal, or electronic notification to the funeral service director, funeral service worker, or body transporter at the time the body is removed from medical examiner custody of the proper precautions to prevent ~~infection.~~ infection, as set forth in Paragraph (f) of this Rule. These precautions are noted in Paragraph (f) of this Rule. The duty to notify shall be considered met if performed by a designated representative of the medical examiner.

~~(b)~~(d) The body of any person who died and is known or reasonably suspected to be infected with smallpox or severe acute respiratory syndrome (SARS) or any person who died and is known to be infected with plague shall not be embalmed. The body shall be enclosed in a ~~strong, tightly~~ sealed outer case ~~which~~ that will prevent leakage or escape of odors as soon as possible after death and before the body is removed from the hospital room, home, building, or other premises where the death occurred. This case shall not be reopened except with the consent of the local health director. Nothing in this Paragraph shall prohibit cremation.

~~(c)~~(e) Persons handling the body of any person who died and is known to be infected with HIV or hepatitis B or any person who died and is known or reasonably suspected to be infected with Jakob-Creutzfeldt or rabies shall be provided ~~written~~ written, verbal, or electronic notification to observe blood and body fluid precautions.

(f) Persons handling the body of any person who died and is known to be infected with COVID-19 shall be provided written, verbal, or electronic notification to observe the COVID-19 guidance for funeral home workers published by the United States Centers for Disease Control and Prevention, which is hereby incorporated by reference, including any subsequent amendments or editions, and available free of charge at: https://www.cdc.gov/coronavirus/2019-ncov/community/funeral-faqs.html.

History Note: *Authority G.S. 130A-144; 130A-146;*
Temporary Rule Eff. February 1, 1988, for a period of 180 days to expire on July 29, 1988;
Eff. March 1, 1988;
Recodified from 15A NCAC 19A .0204 Eff. June 11, 1991;
Temporary Amendment Eff. November 1, 2003;
Amended Eff. April 1, 2004;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. January 9, 2018;
Emergency Amendment Eff. September 25, [~~2020.~~]2020;
Temporary Amendment Eff. December 1, 2020.