REQUEST FOR TECHNICAL CHANGE

AGENCY: Commission for Public Health

RULE CITATION: 10A NCAC 41A .0107

DEADLINE FOR RECEIPT: Thursday, September 9, 2021

***NOTE:* This request when viewed on computer extends 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 call our office to inquire concerning the staff recommendation.

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

In (a)(2), line 8, what is a "machine-readable electronic communication protocol"? Does your regulated public know?

In (a)(3), line 9, consider citing to G.S. 130A-476(g)(1) specifically.

In (a)(4), line 13, is this why you are citing to 42 CFR 493 in your History Note? You may want to instead incorporate them by reference here.

In (c)(1), line 25, I am just checking – the nomenclature is "to onboard to electronic laboratory…"? I am guessing based upon the language in (c)(2), line 35, it is, but I wanted to check.

In (c)(2)(A), line 37, and elsewhere the term is used, what is "telefax"? Is it telefacsimile? Or is it different?

In (e)(1)(B), Page 2, line 12, I take it your regulated public knows what "NPI" is?

In (e)(2), line 18, is this the same survey addressed in (c)(2)(B), on line 4?

In (h), line 29, given that you use the term "immediately" repeatedly in Rule 41A .0101, I take it your regulated public understands what it means here?

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

Amanda J. Reeder
Commission Counsel
Date submitted to agency: August 25, 2021

10A NCAC 41A .0107 is adopted as published in 35:23 NCR 2519–2521 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 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;
Eff. October 1, 2021.

REQUEST FOR TECHNICAL CHANGE

AGENCY: Commission for Public Health

RULE CITATION: 10A NCAC 41A .0212

DEADLINE FOR RECEIPT: Thursday, September 9, 2021

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 call our office to inquire concerning the staff recommendation.

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

In (b), line 10, and elsewhere the term is used, I take it that you are using "reasonably suspected" to mirror the language in G.S. 130A-144?

On line 18, please replace "noted" in "are noted in" with "set forth" This will mirror the language elsewhere in the Rule, such as line 12.

In (c), line 26, I believe you can delete the sentence, "These precautions are noted in Paragraph (f) of this Rule." as it repeats the sentence before it.

In (d), line 30, I am only asking – do you want to retain "tightly" given that there is guidance with "that will prevent leakage or escape" language after it and the adjective makes sense in this context. If you wish to delete it, that is fine as well.

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

Amanda J. Reeder
Commission Counsel
Date submitted to agency: August 25, 2021

10A NCAC 41A .0212 is amended as published in 35:23 NCR 2521–2522 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; 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;
Temporary Amendment Eff. December 1, 2020;
Amended Eff. October 1, 2021.