



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: <input checked="" type="checkbox"/> Adoption <input type="checkbox"/> Amendment <input type="checkbox"/> Repeal
4. Was this an Emergency Rule: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> 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. <input checked="" type="checkbox"/> A serious and unforeseen threat to the public health, safety or welfare. <input type="checkbox"/> The effective date of a recent act of the General Assembly or of the U.S. Congress. Cite: Effective date: <input type="checkbox"/> A recent change in federal or state budgetary policy. Effective date of change: <input type="checkbox"/> A recent federal regulation. Cite: Effective date: <input type="checkbox"/> A recent court order. Cite order: <input type="checkbox"/> State Medical Facilities Plan. <input type="checkbox"/> 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. 2. 20 21

* 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:

Submitted for RRC Review:

Date returned to agency:

TEMPORARY RULES
REQUEST FOR TECHNICAL CHANGE

AGENCY: Commission for Public Health

RULE CITATION: 10A NCAC 41A .0107

DEADLINE FOR RECEIPT: Friday, November 13, 2020

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 this office to inquire concerning the staff recommendation.

In reviewing these rules, the staff determined that the following technical changes need to be made:

In the Temporary Rule-Making Findings of Need Form, please add S.L. 2020-4 as "The effective date of a recent act of the General Assembly" in Box 6.

In (c)(1), what is considered "good faith"? Could you end this sentence after "form to the DPH" and remove "and acts in good faith to onboard to electronic laboratory reporting"? What is the actual requirement here? Is it something like "submits a COVID-19 Laboratory Data Automation Registration form to the Division of Public Health by onboarding to electronic laboratory reporting."

In (c)(2)(A), what "secure telefax"? Delete or define "secure." I assume that this is by fax to you all? Could you just provide the fax information of where you want this sent? I note that this language is elsewhere in your Rule, but you only need to address this once.

In (c)(2)(B), where is this "online survey"? Again, I note that this language is elsewhere, but you only need to address it once.

In (h), delete or define "immediately." Do you mean "upon receiving a positive result" (or something like that)?

Please update your History Note to include the temporary effective date.

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

Amber May
Commission Counsel
Date submitted to agency: November 6, 2020

1 10A NCAC 41A .0107 is adopted under temporary procedures as follows:
2

3 **10A NCAC 41A .0107 REPORTING OF COVID-19 DIAGNOSTIC TEST RESULTS**

4 (a) For purposes of this Rule, the following definitions shall apply:

5 (1) “COVID-19 diagnostic test” means any nucleic acid or antigen test that identifies SARS-CoV-2, the
6 virus that causes COVID-19.

7 (2) “Electronic laboratory reporting” means the automated messaging of laboratory reports sent to the
8 Division of Public Health using a machine-readable electronic communication protocol.

9 (3) “Healthcare provider” means a healthcare provider as defined in G.S. 130A-476(g).

10 (4) “Laboratory” means a facility that performs testing on specimens obtained from humans for the
11 purpose of providing information for health assessment and for the diagnosis, prevention, or
12 treatment of disease and is certified by the United States Department of Health and Human Services
13 under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) and implementing
14 regulations. This definition includes a healthcare provider who performs testing in an on-site facility
15 that meets these requirements.

16 (b) Each person in charge of a laboratory providing diagnostic service in this State shall report the results of all
17 COVID-19 diagnostic tests to the Division of Public Health using electronic laboratory reporting. For purposes of
18 COVID-19, a novel coronavirus under Rule .0101(c)(1) of this Section, the required method of reporting set out in
19 Rules .0101(c) and .0102(d)(3) of this Section shall not apply. The report shall include all of the elements required to
20 be reported under the United States Department of Health and Human Services, laboratory data reporting guidance,
21 which is hereby incorporated by reference, including any subsequent amendments and editions, and available free of
22 charge at <https://www.hhs.gov/sites/default/files/covid-19-laboratory-data-reporting-guidance.pdf>.

23 (c) The requirements set forth in Paragraph (b) of this Rule shall be considered met if a laboratory:

24 (1) submits a COVID-19 Laboratory Data Automation Registration form to the Division of Public
25 Health and acts in good faith to onboard to electronic laboratory reporting. This form shall be
26 submitted within seven calendar days of the date the laboratory starts performing COVID-19
27 diagnostic testing and shall contain the following elements:

28 (A) the name, address, phone number, and CLIA number of the laboratory;

29 (B) the name, address, and phone number of the person in charge of the laboratory or that
30 person’s designee;

31 (C) the type of test performed, testing capacity, and whether the laboratory will use a third-
32 party laboratory to perform part or all of the testing; and

33 (D) if the laboratory will use a third-party laboratory to perform part or all of the testing, the
34 information in Subparagraphs (c)(1)(A)-(B) for the third-party laboratory; and

35 (2) until onboarding to electronic laboratory reporting is complete:

36 (A) reports the results of positive COVID-19 diagnostic tests to the Division of Public Health,
37 including all elements required in Paragraph (b) of this Rule, by secure telefax; and

1 (B) reports the aggregate number of positive and negative nucleic acid COVID-19 diagnostic
2 tests and the aggregate number of positive and negative antigen COVID-19 diagnostic tests
3 per day to the Division of Public Health through an online survey.

4 (d) The requirements set forth in Paragraph (b) of this Rule shall be considered met if a laboratory that completes
5 fewer than 50 total COVID-19 diagnostic tests per week submits results as set out in Subparagraph (c)(2) of this Rule.

6 (e) Healthcare providers who order COVID-19 diagnostic testing in this State shall:

7 (1) report the results of positive COVID-19 diagnostic tests by secure telefax to the local health director
8 in the county or district where the patient resides. The report shall contain:

9 (A) patient first and last name, date of birth, address, county of residence, phone number, sex,
10 race, and ethnicity;

11 (B) provider name, address, phone number, and NPI;

12 (C) the specimen collection date, the test order date, and the test result date;

13 (D) the test result; and

14 (E) all other available elements required in Paragraph (b) of this Rule; and

15 (2) report the aggregate number of positive and negative nucleic acid COVID-19 diagnostic tests and
16 the aggregate number of positive and negative antigen COVID-19 diagnostic tests per day to the
17 Division of Public Health through an online survey.

18 (f) The requirements set forth in Paragraph (e) of this Rule shall be considered met if a healthcare provider:

19 (1) verifies that the laboratory that receives the specimen for testing will report the test result in
20 accordance with Paragraph (b) of this Rule; and

21 (2) includes patient first and last name, date of birth, address, county of residence, phone number, sex,
22 race, ethnicity, and specimen collection date on the lab order.

23 (g) The requirement for healthcare providers to report COVID-19 diagnostic test results, as set out in Paragraph (e)
24 of this Rule, is separate from the requirement for physicians to report suspected infections of COVID-19, a novel
25 coronavirus, including positive COVID-19 diagnostic test results, in accordance with G.S. 130A-135 and Rules
26 .0101(a) and .0102(a) of this Section.

27 (h) Laboratories and healthcare providers who are required to report under this Rule shall report positive COVID-19
28 diagnostic test results immediately and negative COVID-19 diagnostic test results within 24 hours of receiving the
29 result. Results reported to a local health department under this Rule shall be forwarded to the Division of Public Health
30 within 24 hours of receipt by the local health department.

31
32 History Note: Authority G.S. 130A-134; 130A-135; 130A-139; 130A-141; 130A-141.1; S.L. 2020-4, Sec.
33 4.10(a)(1); P.L. 100-578; 42 C.F.R. 493;
34 Emergency Adoption Eff. September 25, 2020.



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 .0212, Handling and Transportation of Bodies
3. Action: <input type="checkbox"/> Adoption <input checked="" type="checkbox"/> Amendment <input type="checkbox"/> Repeal
4. Was this an Emergency Rule: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> 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: 9/30/2020 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. <input checked="" type="checkbox"/> A serious and unforeseen threat to the public health, safety or welfare. <input type="checkbox"/> The effective date of a recent act of the General Assembly or of the U.S. Congress. Cite: Effective date: <input type="checkbox"/> A recent change in federal or state budgetary policy. Effective date of change: <input type="checkbox"/> A recent federal regulation. Cite: Effective date: <input type="checkbox"/> A recent court order. Cite order: <input type="checkbox"/> State Medical Facilities Plan. <input type="checkbox"/> 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. On June 18, 2020, the NC Commission for Public Health received a petition for rulemaking from the North Carolina Board of Funeral Service, requesting that the Commission consider amending rule 10A NCAC 41A .0212 to set out the proper precautions to prevent infection during the handling and transportation of the bodies of persons infected with COVID-19 and require notification of those precautions. Pursuant to G.S. 150B-20, the Commission fully considered and granted the petition at its meeting on August 5, 2020. However, the Commission did not approve the proposed rule language submitted with the petition and directed agency staff to revise the proposed rule language for consideration at a special meeting on September 15, 2020. Notice of this decision was provided in writing to the North Carolina Board of Funeral Service on August 5, 2020. On September 15, 2020, the Commission adopted an amendment to the rule under emergency procedures and approved proceeding with rulemaking under temporary procedures. It is imperative that this rule be quickly amended to address the need identified by the North Carolina Board of Funeral Service for communicable disease control measures to mitigate the risk of disease transmission during the handling and transportation of the bodies of persons infected with COVID-19. 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

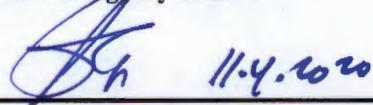
E-Mail: virginia.niehaus@dhhs.nc.gov

Agency contact, if any: Kirsten Leloudis

Phone: (919) 607-0813

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

10. Signature of Agency Head*:



* 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:

Submitted for RRC Review:

Date returned to agency:

TEMPORARY RULES
REQUEST FOR TECHNICAL CHANGE

AGENCY: Commission for Public Health

RULE CITATION: 10A NCAC 41A .0212

DEADLINE FOR RECEIPT: Friday, November 13, 2020

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 this office to inquire concerning the staff recommendation.

In reviewing these rules, the staff determined that the following technical changes need to be made:

In (b), (d), and (e), is “reasonably” in “reasonably suspected” a term of art? If not, please delete or define “reasonably.”

In (b), line 12, delete or define “proper” Here, do you mean those precautions provided in Paragraph (a)? Since there appear to be different precautions depending upon where the patient dies, please make it clear.

In (b), consider deleting “one of the following individuals.” Alternatively, provide the two sets of people in list form.

In (d), line 28, delete or define “strong” and “tightly”

In (d), line 28, change “which” to “that” in “which will prevent”

Please update your History Note to include the temporary effective date.

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

Amber May
Commission Counsel
Date submitted to agency: November 6, 2020

1 10A NCAC 41A .0212 is amended under temporary procedures as follows:

2
3 **10A NCAC 41A .0212 HANDLING AND TRANSPORTATION OF BODIES**

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

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

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

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

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

35 (f) Persons handling the body of any person who died and is known to be infected with COVID-19 shall be provided
36 written, verbal, or electronic notification to observe the COVID-19 guidance for funeral home workers published by
37 the United States Centers for Disease Control and Prevention, which is hereby incorporated by reference, including

1 any subsequent amendments or editions, and available free of charge at: [https://www.cdc.gov/coronavirus/2019-](https://www.cdc.gov/coronavirus/2019-ncov/community/funeral-faqs.html)
2 [ncov/community/funeral-faqs.html](https://www.cdc.gov/coronavirus/2019-ncov/community/funeral-faqs.html).

3

4 *History Note: Authority G.S. 130A-144; 130A-146;*

5 *Temporary Rule Eff. February 1, 1988, for a period of 180 days to expire on July 29, 1988;*

6 *Eff. March 1, 1988;*

7 *Recodified from 15A NCAC 19A .0204 Eff. June 11, 1991;*

8 *Temporary Amendment Eff. November 1, 2003;*

9 *Amended Eff. April 1, 2004;*

10 *Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. January 9,*

11 *2018;*

12 *Emergency Amendment Eff. September 25, 2020.*