



# TEMPORARY RULE-MAKING FINDINGS OF NEED

[Authority G.S. 150B-21.1]

OAH USE ONLY

VOLUME:

ISSUE:

<b>1. Rule-Making Agency:</b> NC Commission for Public Health
<b>2. Rule citation &amp; name:</b> 10A NCAC 41A .0101, Reportable Diseases and Conditions
<b>3. Action:</b> <input type="checkbox"/> Adoption <input checked="" type="checkbox"/> Amendment <input type="checkbox"/> Repeal
<b>4. Was this an Emergency Rule:</b> <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <b>Effective date:</b> 2/17/20
<b>5. Provide dates for the following actions as applicable:</b> a. Proposed Temporary Rule submitted to OAH: 2/5/20 b. Proposed Temporary Rule published on the OAH website: 2/11/20 c. Public Hearing date: 2/24/20 d. Comment Period: 2/5/20 – 3/5/20 e. Notice pursuant to G.S. 150B-21.1(a3)(2): 2/5/20 f. Adoption by agency on: 3/24/20 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)]:
<b>6. Reason for Temporary Action. Attach a copy of any cited law, regulation, or document necessary for the review.</b> <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: <b>Explain:</b> 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 March 23, 2020, over 340,000 confirmed cases and 15,000 deaths had been reported from 173 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 March 23, over 30,000 cases had been reported in the U.S., and over 260 cases 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. No vaccine or specific treatment for this infection is available.  It is imperative that public health authorities be rapidly notified when infections of novel coronavirus or deaths caused by novel coronavirus are suspected so that appropriate control and mitigation measures can be quickly implemented to prevent further spread. Rapid notification of suspected infections and deaths will increase the timeliness of testing, case identification, and implementation of control and mitigation measures to protect the public's health. For this reason, pursuant to G.S. 130A-141.1, the State Health Director issued a Temporary Order requiring immediate reporting of novel coronavirus infections effective February 3, 2020 and another Temporary Order requiring reporting of deaths due to novel coronavirus infection within 24 hours effective March 23, 2020. This temporary rule is needed to continue these reporting requirements while a permanent amendment is pursued. Immediate adoption of this temporary rule is required due to the serious and unforeseen threat 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: 919 707-5006

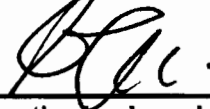
E-Mail: virginia.niehaus@dhhs.nc.gov

**Agency contact, if any: Kirsten Leloudis**

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**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 .0101

**DEADLINE FOR RECEIPT: Thursday, April 9, 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:

*Please remove the "DRAFT" watermark from each page of the Rule. Please do not attempt to show this as a change – simple do it.*

*On Page 6, in the History Note, please add the proposed effective date of this temporary amendment. That will be April 24, 2020.*

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: April 3, 2020

1 10A NCAC 41A .0101 is amended **with changes** under temporary procedures as follows:

2  
3 **CHAPTER 41 - EPIDEMIOLOGY HEALTH**

4  
5 **SUBCHAPTER 41A - COMMUNICABLE DISEASE CONTROL**

6  
7 **SECTION .0100 - COMMUNICABLE DISEASE CONTROL**

8  
9 **10A NCAC 41A .0101 REPORTABLE DISEASES AND CONDITIONS**

10 (a) The following named diseases and conditions are declared to be dangerous to the public health and are hereby  
11 made reportable within the time period specified after the disease or condition is reasonably suspected to exist:

- 12 (1) acquired immune deficiency syndrome (AIDS) - 24 hours;
- 13 (2) anthrax - immediately;
- 14 (3) botulism - immediately;
- 15 (4) brucellosis - 7 days;
- 16 (5) campylobacter infection - 24 hours;
- 17 (6) Candida auris - 24 hours;
- 18 (7) Carbapenem-Resistant Enterobacteriaceae (CRE) – 24 hours;
- 19 (8) chancroid - 24 hours;
- 20 (9) chikungunya virus infection - 24 hours;
- 21 (10) chlamydial infection (laboratory confirmed) - 7 days;
- 22 (11) cholera - 24 hours;
- 23 (12) Creutzfeldt-Jakob disease – 7 days;
- 24 (13) cryptosporidiosis – 24 hours;
- 25 (14) cyclosporiasis – 24 hours;
- 26 (15) dengue - 7 days;
- 27 (16) diphtheria - 24 hours;
- 28 (17) Escherichia coli, shiga toxin-producing - 24 hours;
- 29 (18) ehrlichiosis – 7 days;
- 30 (19) encephalitis, arboviral - 7 days;
- 31 (20) foodborne disease, including Clostridium perfringens, staphylococcal, Bacillus cereus, and other  
32 and unknown causes - 24 hours;
- 33 (21) gonorrhea - 24 hours;
- 34 (22) granuloma inguinale - 24 hours;
- 35 (23) Haemophilus influenzae, invasive disease - 24 hours;

- 1 (24) Hantavirus infection – 7 days;  
2 (25) Hemolytic-uremic syndrome – 24 hours;  
3 (26) Hemorrhagic fever virus infection – immediately;  
4 (27) hepatitis A - 24 hours;  
5 (28) hepatitis B - 24 hours;  
6 (29) hepatitis B carriage - 7 days;  
7 (30) hepatitis C, acute – 7 days;  
8 (31) human immunodeficiency virus (HIV) infection confirmed - 24 hours;  
9 (32) influenza virus infection causing death – 24 hours;  
10 (33) legionellosis - 7 days;  
11 (34) leprosy – 7 days;  
12 (35) leptospirosis - 7 days;  
13 (36) listeriosis – 24 hours;  
14 (37) Lyme disease - 7 days;  
15 (38) Lymphogranuloma venereum - 7 days;  
16 (39) malaria - 7 days;  
17 (40) measles (rubeola) - 24 hours;  
18 (41) meningitis, pneumococcal - 7 days;  
19 (42) meningococcal disease - 24 hours;  
20 (43) Middle East respiratory syndrome (MERS) - 24 hours;  
21 (44) monkeypox – 24 hours;  
22 (45) mumps - 7 days;  
23 (46) nongonococcal urethritis - 7 days;  
24 (47) novel coronavirus infection causing death – 24 hours;  
25 ~~(47)~~ (48) novel coronavirus infection – immediately;  
26 ~~(48)~~(47)(49) novel influenza virus infection – immediately;  
27 ~~(49)~~(48)(50) plague - immediately;  
28 ~~(50)~~(49)(51) paralytic poliomyelitis - 24 hours;  
29 ~~(51)~~(50)(52) pelvic inflammatory disease – 7 days;  
30 ~~(52)~~(51)(53) psittacosis - 7 days;  
31 ~~(53)~~(52)(54) Q fever - 7 days;  
32 ~~(54)~~(53)(55) rabies, human - 24 hours;  
33 ~~(55)~~(54)(56) Rocky Mountain spotted fever - 7 days;  
34 ~~(56)~~(55)(57) rubella - 24 hours;  
35 ~~(57)~~(56)(58) rubella congenital syndrome - 7 days;

- 1           ~~(58)~~~~(57)~~~~(59)~~ salmonellosis - 24 hours;
- 2           ~~(59)~~~~(58)~~~~(60)~~ severe acute respiratory syndrome (SARS) – 24 hours;
- 3           ~~(60)~~~~(59)~~~~(61)~~ shigellosis - 24 hours;
- 4           ~~(61)~~~~(60)~~~~(62)~~ smallpox - immediately;
- 5           ~~(62)~~~~(61)~~~~(63)~~ Staphylococcus aureus with reduced susceptibility to vancomycin – 24 hours;
- 6           ~~(63)~~~~(62)~~~~(64)~~ streptococcal infection, Group A, invasive disease - 7 days;
- 7           ~~(64)~~~~(63)~~~~(65)~~ syphilis - 24 hours;
- 8           ~~(65)~~~~(64)~~~~(66)~~ tetanus - 7 days;
- 9           ~~(66)~~~~(65)~~~~(67)~~ toxic shock syndrome - 7 days;
- 10          ~~(67)~~~~(66)~~~~(68)~~ trichinosis - 7 days;
- 11          ~~(68)~~~~(67)~~~~(69)~~ tuberculosis - 24 hours;
- 12          ~~(69)~~~~(68)~~~~(70)~~ tularemia – immediately;
- 13          ~~(70)~~~~(69)~~~~(71)~~ typhoid - 24 hours;
- 14          ~~(71)~~~~(70)~~~~(72)~~ typhoid carriage (Salmonella typhi) - 7 days;
- 15          ~~(72)~~~~(71)~~~~(73)~~ typhus, epidemic (louse-borne) - 7 days;
- 16          ~~(73)~~~~(72)~~~~(74)~~ vaccinia – 24 hours;
- 17          ~~(74)~~~~(73)~~~~(75)~~ vibrio infection (other than cholera) – 24 hours;
- 18          ~~(75)~~~~(74)~~~~(76)~~ whooping cough – 24 hours; and
- 19          ~~(76)~~~~(75)~~~~(77)~~ yellow fever - 7 days.

20       (b) For purposes of reporting, "confirmed human immunodeficiency virus (HIV) infection" is defined as a positive  
21 virus culture, repeatedly reactive EIA antibody test confirmed by western blot or indirect immunofluorescent antibody  
22 test, positive nucleic acid detection (NAT) test, or other confirmed testing method approved by the Director of the  
23 State Public Health Laboratory conducted on or after February 1, 1990. In selecting additional tests for approval, the  
24 Director of the State Public Health Laboratory shall consider whether such tests have been approved by the federal  
25 Food and Drug Administration, recommended by the federal Centers for Disease Control and Prevention, and  
26 endorsed by the Association of Public Health Laboratories.

27       (c) In addition to the laboratory reports for Mycobacterium tuberculosis, Neisseria gonorrhoeae, and syphilis specified  
28 in G.S. 130A-139, laboratories shall report using electronic laboratory reporting (ELR), secure telecommunication, or  
29 paper reports.

- 30           (1) Isolation or other specific identification of the following organisms or their products from human  
31 clinical specimens:
  - 32           (A) Any hantavirus or hemorrhagic fever virus.
  - 33           (B) Arthropod-borne virus (any type).
  - 34           (C) Bacillus anthracis, the cause of anthrax.
  - 35           (D) Bordetella pertussis, the cause of whooping cough (pertussis).
  - 36           (E) Borrelia burgdorferi, the cause of Lyme disease (confirmed tests).

- 1 (F) Brucella spp., the causes of brucellosis.
- 2 (G) Campylobacter spp., the causes of campylobacteriosis.
- 3 (H) Candida auris.
- 4 (I) Carbapenem-Resistant Enterobacteriaceae (CRE).
- 5 (J) Chlamydia trachomatis, the cause of genital chlamydial infection, conjunctivitis (adult and  
6 newborn) and pneumonia of newborns.
- 7 (K) Clostridium botulinum, a cause of botulism.
- 8 (L) Clostridium tetani, the cause of tetanus.
- 9 (M) Coronavirus, novel human strain.
- 10 ~~(N)(M)~~ Corynebacterium diphtheriae, the cause of diphtheria.
- 11 ~~(O)(N)~~ Coxiella burnetii, the cause of Q fever.
- 12 ~~(P)(O)~~ Cryptosporidium parvum, the cause of human cryptosporidiosis.
- 13 ~~(Q)(P)~~ Cyclospora cayetanensis, the cause of cyclosporiasis.
- 14 ~~(R)(Q)~~ Ehrlichia spp., the causes of ehrlichiosis.
- 15 ~~(S)(R)~~ Shiga toxin-producing Escherichia coli, a cause of hemorrhagic colitis, hemolytic uremic  
16 syndrome, and thrombotic thrombocytopenic purpura.
- 17 ~~(T)(S)~~ Francisella tularensis, the cause of tularemia.
- 18 ~~(U)(T)~~ Hepatitis B virus or any component thereof, such as hepatitis B surface antigen.
- 19 ~~(V)(U)~~ Human Immunodeficiency Virus, the cause of AIDS.
- 20 ~~(W)(V)~~ Legionella spp., the causes of legionellosis.
- 21 ~~(X)(W)~~ Leptospira spp., the causes of leptospirosis.
- 22 ~~(Y)(X)~~ Listeria monocytogenes, the cause of listeriosis.
- 23 ~~(Z)(Y)~~ Middle East respiratory syndrome virus.
- 24 ~~(AA)(Z)~~ Monkeypox.
- 25 ~~(BB)(AA)~~ Mycobacterium leprae, the cause of leprosy.
- 26 ~~(CC)(BB)~~ Plasmodium falciparum, P. malariae, P. ovale, and P. vivax, the causes of malaria in  
27 humans.
- 28 ~~(DD)(CC)~~ Poliovirus (any), the cause of poliomyelitis.
- 29 ~~(EE)(DD)~~ Rabies virus.
- 30 ~~(FF)(EE)~~ Rickettsia rickettsii, the cause of Rocky Mountain spotted fever.
- 31 ~~(GG)(FF)~~ Rubella virus.
- 32 ~~(HH)(GG)~~ Salmonella spp., the causes of salmonellosis.
- 33 ~~(II)(HH)~~ Shigella spp., the causes of shigellosis.
- 34 ~~(JJ)(II)~~ Smallpox virus, the cause of smallpox.
- 35 ~~(KK)(JJ)~~ Staphylococcus aureus with reduced susceptibility to vanomycin.
- 36 ~~(LL)(KK)~~ Trichinella spiralis, the cause of trichinosis.
- 37 (MM)(LL) Vaccinia virus.

1 ~~(NN)(MM)~~ *Vibrio* spp., the causes of cholera and other vibrioses.

2 ~~(OO)(NN)~~ Yellow fever virus.

3 ~~(PP)(OO)~~ *Yersinia pestis*, the cause of plague.

4 (2) Isolation or other specific identification of the following organisms from normally sterile human  
5 body sites:

6 (A) Group A *Streptococcus pyogenes* (group A streptococci).

7 (B) *Haemophilus influenzae*, serotype b.

8 (C) *Neisseria meningitidis*, the cause of meningococcal disease.

9 (3) Positive serologic test results, as specified, for the following infections:

10 (A) Fourfold or greater changes or equivalent changes in serum antibody titers to:

11 (i) Any arthropod-borne viruses associated with meningitis or encephalitis in a  
12 human.

13 (ii) Any hantavirus or hemorrhagic fever virus.

14 (iii) *Chlamydia psittaci*, the cause of psittacosis.

15 (iv) *Coxiella burnetii*, the cause of Q fever.

16 (v) Dengue virus.

17 (vi) *Ehrlichia* spp., the causes of ehrlichiosis.

18 (vii) Measles (rubeola) virus.

19 (viii) Mumps virus.

20 (ix) *Rickettsia rickettsii*, the cause of Rocky Mountain spotted fever.

21 (x) Rubella virus.

22 (xi) Yellow fever virus.

23 (B) The presence of IgM serum antibodies to:

24 (i) *Chlamydia psittaci*.

25 (ii) Hepatitis A virus.

26 (iii) Hepatitis B virus core antigen.

27 (iv) Rubella virus.

28 (v) Rubeola (measles) virus.

29 (vi) Yellow fever virus.

30 (4) Laboratory results from tests to determine the absolute and relative counts for the T-helper (CD4)  
31 subset of lymphocytes and all results from tests to determine HIV viral load.

32 (5) Identification of CRE from a clinical specimen associated with either infection or colonization,  
33 including all susceptibility results and all phenotypic or molecular test results.

34 (d) Laboratories utilizing electronic laboratory reporting (ELR) shall report in addition to those listed under Paragraph  
35 (c) of this Rule:

36 (1) All positive laboratory results from tests used to diagnosis chronic Hepatitis C Infection, including  
37 the following:

- 1 (A) Hepatitis C virus antibody tests (including the test specific signal to cut-off (s/c) ratio);  
2 (B) Hepatitis C nucleic acid tests;  
3 (C) Hepatitis C antigen(s) tests; and  
4 (D) Hepatitis C genotypic tests.  
5 (2) All HIV genotypic test results, including when available:  
6 (A) The entire nucleotide sequence; or  
7 (B) The pol region sequence (including all regions: protease (PR)/reverse transcriptase (RT)  
8 and integrase (INI) genes, if available).  
9 (e) For the purposes of reporting, Carbapenem-Resistant Enterobacteriaceae (CRE) are defined as:  
10 (1) Enterobacter spp, E.coli or Klebsiella spp positive for a known carbapenemase resistance  
11 mechanism or positive on a phenotypic test for carbapenemase production; or  
12 (2) Enterobacter spp, E.coli or Klebsiella spp resistant to any carbapenem in the absence of  
13 carbapenemase resistance mechanism testing or phenotypic testing for carbapenemase production.  
14

15 *History Note: Authority G.S. 130A-134; 130A-135; 130A-139; 130A-141;*  
16 *Amended Eff. October 1, 1994; February 1, 1990;*  
17 *Temporary Amendment Eff. July 1, 1997;*  
18 *Amended Eff. August 1, 1998;*  
19 *Temporary Amendment Eff. February 13, 2003; October 1, 2002; February 18, 2002; June 1, 2001;*  
20 *Amended Eff. April 1, 2003;*  
21 *Temporary Amendment Eff. November 1, 2003; May 16, 2003;*  
22 *Amended Eff. January 1, 2005; April 1, 2004;*  
23 *Temporary Amendment Eff. June 1, 2006;*  
24 *Amended Eff. April 1, 2008; November 1, 2007; October 1, 2006;*  
25 *Temporary Amendment Eff. January 1, 2010;*  
26 *Temporary Amendment Expired September 11, 2011;*  
27 *Amended Eff. July 1, 2013;*  
28 *Temporary Amendment Eff. December 2, 2014;*  
29 *Amended Eff. October 1, 2015;*  
30 *Emergency Amendment Eff. March 1, 2016;*  
31 *Temporary Amendment Eff. July 1, 2016;*  
32 *Amended Eff. January 1, 2018; October 1, 2016;*  
33 *Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. January 9,*  
34 *2018;*  
35 *Amended Eff. October 1, 2018;*  
36 *Emergency Amendment Eff. February 17, 2020.*