



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: February 5, 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 .0101

The Commission for Public Health (CPH) has adopted an amendment to 10A NCAC 41A .0101 under emergency procedures and simultaneously proposed to amend 10A NCAC 41A .0101 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 rule actions update the communicable diseases and conditions reporting requirements to include novel coronavirus. Novel coronavirus (nCoV) was identified as the cause of an emerging infectious disease outbreak in December 2019 in Wuhan, Hubei Province, China. This nCoV causes respiratory illness ranging in severity from milder illness to death. As of February 4, 2020, over 20,500 confirmed cases and 427 deaths had been reported, almost all from China, but also from 25 other countries including the United States. The ongoing outbreak has already surpassed the total number of the previous outbreaks of SARS (Sudden Acute Respiratory Syndrome) and MERS (Middle Eastern Respiratory Syndrome). The first U.S. case was reported in a traveler returning from Wuhan on January 21, 2020 in Washington State. The North Carolina Division of Public Health is working closely with the Centers for Disease Control and Prevention (CDC) to monitor and prepare for possible cases in North Carolina. No vaccine or specific treatment for this infection is available. Rapid implementation of control measures may help limit spread if cases are reported once identified.

It is imperative that public health authorities be rapidly notified when these infections are suspected so that appropriate control measures can be implemented to prevent further spread. Currently, diagnostic testing is only available at CDC through coordination with the State Laboratory for Public Health. Rapid notification of suspected infections will increase the timeliness of testing, case identification, and implementation of control measures to protect the public's health. For this reason, the State Health Director issued a Temporary Order pursuant to G.S. 130A-141.1 requiring immediate reporting of novel coronavirus effective February 3, 2020. An emergency rule was adopted on February 5, 2020 to continue the reporting requirement by rule while temporary and eventually permanent rules are pursued. Immediate adoption of the rule is required due to the serious and unforeseen threat posed by this infectious disease.

The public hearing on the temporary rule is scheduled for Monday, February 24, 2020 at 2:00 p.m. in the Cardinal Conference Room, Building 3, 5605 Six Forks Road, Raleigh, NC 27609.

NC DEPARTMENT OF HEALTH AND HUMAN SERVICES • DIVISION OF PUBLIC HEALTH

LOCATION: 5605 Six Forks Road, Building 3, Raleigh, NC 27609
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AN EQUAL OPPORTUNITY / AFFIRMATIVE ACTION EMPLOYER

CPH is accepting public comments on the temporary rule from February 5, 2020 – March 5, 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 questions related to this memorandum or the proposed rules, please contact Dr. Jean-Marie Maillard, Medical Director, Communicable Disease Branch, Epidemiology Section, Division of Public Health at (919) 546-1650.

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
Dr. Jean-Maire Maillard, Medical Director, Epidemiology Section, Division of Public Health
Ms. Kirsten Leloudis, Program Manager, Regulatory and Legal Affairs, Division of Public Health

1 10A NCAC 41A .0101 is amended under emergency 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 – immediately;
- 25 (48)(47) novel influenza virus infection – immediately;
- 26 (49)(48) plague - immediately;
- 27 (50)(49) paralytic poliomyelitis - 24 hours;
- 28 (51)(50) pelvic inflammatory disease – 7 days;
- 29 (52)(51) psittacosis - 7 days;
- 30 (53)(52) Q fever - 7 days;
- 31 (54)(53) rabies, human - 24 hours;
- 32 (55)(54) Rocky Mountain spotted fever - 7 days;
- 33 (56)(55) rubella - 24 hours;
- 34 (57)(56) rubella congenital syndrome - 7 days;

- 1 ~~(58)~~~~(57)~~ salmonellosis - 24 hours;
2 ~~(59)~~~~(58)~~ severe acute respiratory syndrome (SARS) – 24 hours;
3 ~~(60)~~~~(59)~~ shigellosis - 24 hours;
4 ~~(61)~~~~(60)~~ smallpox - immediately;
5 ~~(62)~~~~(61)~~ Staphylococcus aureus with reduced susceptibility to vancomycin – 24 hours;
6 ~~(63)~~~~(62)~~ streptococcal infection, Group A, invasive disease - 7 days;
7 ~~(64)~~~~(63)~~ syphilis - 24 hours;
8 ~~(65)~~~~(64)~~ tetanus - 7 days;
9 ~~(66)~~~~(65)~~ toxic shock syndrome - 7 days;
10 ~~(67)~~~~(66)~~ trichinosis - 7 days;
11 ~~(68)~~~~(67)~~ tuberculosis - 24 hours;
12 ~~(69)~~~~(68)~~ tularemia – immediately;
13 ~~(70)~~~~(69)~~ typhoid - 24 hours;
14 ~~(71)~~~~(70)~~ typhoid carriage (Salmonella typhi) - 7 days;
15 ~~(72)~~~~(71)~~ typhus, epidemic (louse-borne) - 7 days;
16 ~~(73)~~~~(72)~~ vaccinia – 24 hours;
17 ~~(74)~~~~(73)~~ vibrio infection (other than cholera) – 24 hours;
18 ~~(75)~~~~(74)~~ whooping cough – 24 hours; and
19 ~~(76)~~~~(75)~~ 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; ~~2018~~.*
36 *Emergency Amendment Eff. February 17, 2020.*
37

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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.
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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