

REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: Commission for Public Health

RULE CITATION: 10A NCAC 41A .0101

DEADLINE FOR RECEIPT: September 19, 2024

PLEASE NOTE: This request may extend to 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 email the reviewing attorney to inquire concerning the staff recommendation.

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

Generally, to the Rule: Is there a rule which prescribes the information that must be submitted as part of the report(s)?

Page 1, Line 10: Explain the Commission's authority to declare dangers to public health?

Page 1, Line 11: "Reportable" implies it is optional. Its like which is void and that which is voidable.

Consider: This Subchapter provides a list of communicable diseases and communicable conditions which shall be reported pursuant to Article 6 of Chapter 130A of the North Carolina General Statutes and this Subchapter.

Page 4, Line 2: What is the "electronic laboratory reporting?"

Page 4, Line 2: Does the ELR require certain information be provided? Eg. The reporting doctor's name, or the county of residence of the disease or condition. If not, identify the rule, if any, which sets forth the information which must be reported.

Page 4, Line 2: Define "secure" and "telecommunication."

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

William W. Peaslee
Commission Counsel

Date submitted to agency: September 5, 2024

1 10A NCAC 41A .0101 is amended as published in 38:23 NCR 1497-1500 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) acute flaccid myelitis – 7 days;
- 14 (3) anaplasmosis – 7 days;
- 15 (4) anthrax - immediately;
- 16 (5) arboviral infection, neuroinvasive – 7 days;
- 17 (6) babesiosis – 7 days;
- 18 (7) botulism - immediately;
- 19 (8) brucellosis - 7 days;
- 20 (9) campylobacter infection - 24 hours;
- 21 (10) Candida auris - 24 hours;
- 22 (11) ~~Carbapenem-Resistant Enterobacteriaceae (CRE)~~ Carbapenemase-producing organisms (CPO) – 24
- 23 hours;
- 24 (12) chancroid - 24 hours;
- 25 (13) chikungunya virus infection - 24 hours;
- 26 (14) chlamydial infection (laboratory confirmed) - 7 days;
- 27 (15) cholera - 24 hours;
- 28 (16) Creutzfeldt-Jakob disease – 7 days;
- 29 (17) Cronobacter infection, invasive, in individuals less than twelve months of age – 24 hours;
- 30 ~~(18)(17)~~ cryptosporidiosis – 24 hours;
- 31 ~~(19)(18)~~ cyclosporiasis – 24 hours;
- 32 ~~(20)(19)~~ dengue - 7 days;
- 33 ~~(21)(20)~~ diphtheria - 24 hours;
- 34 ~~(22)(21)~~ Escherichia coli, shiga toxin-producing infection - 24 hours;
- 35 ~~(23)(22)~~ ehrlichiosis – 7 days;

~~(24)~~~~(23)~~ foodborne disease, including Clostridium perfringens, staphylococcal, Bacillus cereus, and other
and unknown causes - 24 hours;
~~(25)~~~~(24)~~ gonorrhea - 24 hours;
~~(26)~~~~(25)~~ granuloma inguinale - 24 hours;
~~(27)~~~~(26)~~ Haemophilus influenzae, invasive disease - 24 hours;
~~(28)~~~~(27)~~ Hantavirus infection – 7 days;
~~(29)~~~~(28)~~ Hemolytic-uremic syndrome – 24 hours;
~~(30)~~~~(29)~~ Hemorrhagic fever virus infection – immediately;
~~(31)~~~~(30)~~ hepatitis A - 24 hours;
~~(32)~~~~(31)~~ hepatitis B - 24 hours;
~~(33)~~~~(32)~~ hepatitis B carriage - 7 days;
~~(34)~~~~(33)~~ hepatitis C, acute – 7 days;
~~(35)~~~~(34)~~ human immunodeficiency virus (HIV) infection confirmed - 24 hours;
~~(36)~~~~(35)~~ influenza virus infection causing death – 24 hours;
~~(37)~~~~(36)~~ legionellosis - 7 days;
~~(38)~~~~(37)~~ leprosy – 7 days;
~~(39)~~~~(38)~~ leptospirosis - 7 days;
~~(40)~~~~(39)~~ listeriosis – 24 hours;
~~(41)~~~~(40)~~ Lyme disease - 7 days;
~~(42)~~~~(41)~~ Lymphogranuloma venereum - 7 days;
~~(43)~~~~(42)~~ malaria - 7 days;
~~(44)~~~~(43)~~ measles (rubeola) - immediately;
~~(45)~~~~(44)~~ meningitis, pneumococcal - 7 days;
~~(46)~~~~(45)~~ meningococcal disease - 24 hours;
~~(47)~~~~(46)~~ Middle East respiratory syndrome (MERS) - 24 hours;
~~(48)~~~~(47)~~ ~~monkeypox~~ mpox – 24 hours;
~~(49)~~~~(48)~~ mumps - 7 days;
~~(50)~~~~(49)~~ nongonococcal urethritis - 7 days;
~~(51)~~~~(50)~~ novel coronavirus infection causing death – 24 hours;
~~(52)~~~~(51)~~ novel coronavirus infection – immediately;
~~(53)~~~~(52)~~ novel influenza virus infection – immediately;
~~(54)~~~~(53)~~ plague - immediately;
~~(55)~~~~(54)~~ paralytic poliomyelitis - 24 hours;
~~(56)~~~~(55)~~ pelvic inflammatory disease – 7 days;
~~(57)~~~~(56)~~ psittacosis - 7 days;

~~(58)(57)~~ Q fever - 7 days;
~~(59)(58)~~ rabies, human - 24 hours;
~~(60)(59)~~ rubella - 24 hours;
~~(61)(60)~~ rubella congenital syndrome - 7 days;
~~(62)(61)~~ salmonellosis - 24 hours;
(63) salmonella typhi infection – 24 hours;
(64) salmonella paratyphi infection – 24 hours;
~~(65)(62)~~ severe acute respiratory syndrome (SARS) – 24 hours;
~~(66)(63)~~ shigellosis - 24 hours;
~~(67)(64)~~ smallpox - immediately;
~~(68)(65)~~ spotted fever rickettsiosis – 7 days;
~~(69)(66)~~ Staphylococcus aureus with reduced susceptibility to vancomycin – 24 hours;
~~(70)(67)~~ streptococcal infection, Group A, invasive disease - 7 days;
~~(71)(68)~~ syphilis - 24 hours;
~~(72)(69)~~ tetanus - 7 days;
~~(73)(70)~~ toxic shock syndrome - 7 days;
~~(74)(71)~~ trichinosis - 7 days;
~~(75)(72)~~ tuberculosis - 24 hours;
~~(76)(73)~~ tularemia – immediately;
~~(74) — typhoid - 24 hours;~~
~~(75) — typhoid carriage (Salmonella typhi) - 7 days;~~
~~(77)(76)~~ typhus, epidemic (louse-borne) - 7 days;
~~(78)(77)~~ vaccinia – 24 hours;
~~(79)(78)~~ varicella – 24 hours;
~~(80)(79)~~ vibrio infection (other than cholera) – 24 hours;
~~(81)(80)~~ whooping cough – 24 hours;
~~(82)(81)~~ yellow fever – 7 days; and
~~(83)(82)~~ zika virus – 24 hours.

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

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

(1) Isolation or other specific identification of the following organisms or their products from human clinical specimens:

- (A) *Anaplasma* spp., the causes of anaplasmosis.
- (B) Any hantavirus.
- (C) Any hemorrhagic fever virus.
- (D) Arthropod-borne virus (any type).
- (E) *Babesia* spp., the cause of babesiosis.
- (F) *Bacillus anthracis*, the cause of anthrax.
- (G) *Bordetella pertussis*, the cause of whooping cough (pertussis).
- (H) *Borrelia burgdorferi*, the cause of Lyme disease (confirmed tests).
- (I) *Brucella* spp., the causes of brucellosis.
- (J) *Campylobacter* spp., the causes of campylobacteriosis.
- (K) *Candida auris*.
- (L) ~~Carbapenem-Resistant Enterobacteriaceae (CRE)~~. Carbapenemase-producing organisms (CPO).
- (M) *Chlamydia trachomatis*, the cause of genital chlamydial infection, conjunctivitis (adult and newborn) and pneumonia of newborns.
- (N) *Clostridium botulinum*, a cause of botulism.
- (O) *Clostridium tetani*, the cause of tetanus.
- (P) Coronavirus, novel human strain.
- (Q) *Corynebacterium diphtheriae*, the cause of diphtheria.
- (R) *Coxiella burnetii*, the cause of Q fever.
- (S) *Cryptosporidium* spp., the cause of human cryptosporidiosis.
- (T) *Cyclospora cayetanensis*, the cause of cyclosporiasis.
- (U) Dengue virus.
- (V) *Ehrlichia* spp., the causes of ehrlichiosis.
- (W) Shiga toxin-producing *Escherichia coli*, a cause of hemorrhagic colitis, hemolytic uremic syndrome, and thrombotic thrombocytopenic purpura.
- (X) *Francisella tularensis*, the cause of tularemia.
- (Y) Hepatitis A virus.
- (Z) Hepatitis B virus or any component thereof, such as hepatitis B surface antigen.
- (AA) Human Immunodeficiency Virus, the cause of AIDS.
- (BB) *Legionella* spp., the causes of legionellosis.
- (CC) *Leptospira* spp., the causes of leptospirosis.

- (DD) *Listeria monocytogenes*, the cause of listeriosis.
 - (EE) Measles virus.
 - (FF) Middle East respiratory syndrome virus.
 - (GG) ~~Monkeypox~~. Mpox.
 - (HH) Mumps virus.
 - (II) *Mycobacterium leprae*, the cause of leprosy.
 - (JJ) *Plasmodium falciparum*, *P. malariae*, *P. ovale*, and *P. vivax*, the causes of malaria in humans.
 - (KK) Poliovirus (any), the cause of poliomyelitis.
 - (LL) Rabies virus.
 - (MM) *Rickettsia* spp., the cause of spotted fever rickettsiosis.
 - (NN) Rubella virus.
 - (OO) *Salmonella* spp., the causes of ~~salmonellosis~~. salmonellosis, s. typhi infection, and s. paratyphi infection.
 - (PP) *Shigella* spp., the causes of shigellosis.
 - (QQ) Smallpox virus, the cause of smallpox.
 - (RR) *Staphylococcus aureus* with reduced susceptibility to vancomycin.
 - (SS) *Trichinella spiralis*, the cause of trichinosis.
 - (TT) Vaccinia virus.
 - (UU) Varicella virus.
 - (VV) *Vibrio* spp., the causes of cholera and other vibrioses.
 - (WW) Yellow fever virus.
 - (XX) *Yersinia pestis*, the cause of plague.
 - (YY) Zika virus.
- (2) Isolation or other specific identification of the following organisms from normally sterile human body sites:
- (A) *Cronobacter* spp., if isolated or identified from individuals less than twelve months of age.
 - (B) Group A *Streptococcus pyogenes* (group A streptococci).
 - ~~(B)~~(C) *Haemophilus influenzae*, serotype b.
 - ~~(C)~~(D) *Neisseria meningitidis*, the cause of meningococcal disease.
- (3) Positive serologic test results, as specified, for the following infections:
- (A) Fourfold or greater changes or equivalent changes in serum antibody titers to:
 - (i) Any arthropod-borne virus associated with neuroinvasive disease.
 - (ii) *Anaplasma* spp., the cause of anaplasmosis.
 - (iii) Any hantavirus or hemorrhagic fever virus.
 - (iv) *Chlamydia psittaci*, the cause of psittacosis.
 - (v) Chikungunya virus.

- (vi) Coxiella burnetii, the cause of Q fever.
 - (vii) Dengue virus.
 - (viii) Ehrlichia spp., the causes of ehrlichiosis.
 - (ix) Measles (rubeola) virus.
 - (x) Mumps virus.
 - (xi) Rickettsia rickettsii, the cause of Rocky Mountain spotted fever.
 - (xii) Rubella virus.
 - (xiii) Varicella virus.
 - (xiv) Yellow fever virus.
- (B) The presence of IgM serum antibodies to:
- (i) Any arthropod-borne virus associated with neuroinvasive disease.
 - (ii) Chikungunya virus.
 - (iii) Chlamydia psittaci.
 - (iv) Dengue virus.
 - (v) Hepatitis A virus.
 - (vi) Hepatitis B virus core antigen.
 - (vii) Mumps virus.
 - (viii) Rubella virus.
 - (ix) Rubeola (measles) virus.
 - (x) Yellow fever virus.
- (4) Laboratory results from tests to determine the absolute and relative counts for the T-helper (CD4) subset of lymphocytes and all results from tests to determine HIV viral load.
- (5) Identification of ~~CPE~~ CPO from a clinical specimen associated with either infection or colonization, including all susceptibility results and all phenotypic or molecular test results.
- (d) Laboratories utilizing electronic laboratory reporting (ELR) shall report in addition to those listed under Paragraph (c) of this Rule:
- (1) All positive laboratory results from tests used to diagnosis chronic Hepatitis C Infection, including the following:
 - (A) Hepatitis C virus antibody tests (including the test specific signal to cut-off (s/c) ratio);
 - (B) Hepatitis C nucleic acid tests;
 - (C) Hepatitis C antigen(s) tests; and
 - (D) Hepatitis C genotypic tests.
 - (2) All HIV genotypic test results, including when available:
 - (A) The entire nucleotide sequence; or
 - (B) The pol region sequence (including all regions: protease (PR)/reverse transcriptase (RT) and integrase (INI) genes, if available).
 - (3) All test results for Interferon Gamma Release Assays.

(e) For the purposes of reporting, Carbapenem-Resistant Enterobacteriaceae (CRE) are defined as:

- ~~(1) Enterobacter spp., E.coli or Klebsiella spp positive for a known carbapenemase resistance mechanism or positive on a phenotypic test for carbapenemase production; or~~
- ~~(2) Enterobacter spp., E.coli or Klebsiella spp resistant to any carbapenem in the absence of carbapenemase resistance mechanism testing or phenotypic testing for carbapenemase production.~~

History Note: Authority G.S. 130A-134; 130A-135; 130A-139; 130A-141;
Amended Eff. October 1, 1994; February 1, 1990;
Temporary Amendment Eff. July 1, 1997;
Amended Eff. August 1, 1998;
Temporary Amendment Eff. February 13, 2003; October 1, 2002; February 18, 2002; June 1, 2001;
Amended Eff. April 1, 2003;
Temporary Amendment Eff. November 1, 2003; May 16, 2003;
Amended Eff. January 1, 2005; April 1, 2004;
Temporary Amendment Eff. June 1, 2006;
Amended Eff. April 1, 2008; November 1, 2007; October 1, 2006;
Temporary Amendment Eff. January 1, 2010;
Temporary Amendment Expired September 11, 2011;
Amended Eff. July 1, 2013;
Temporary Amendment Eff. December 2, 2014;
Amended Eff. October 1, 2015;
Emergency Amendment Eff. March 1, 2016;
Temporary Amendment Eff. July 1, 2016;
Amended Eff. January 1, 2018; October 1, 2016;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. January 9,
2018;
Amended Eff. October 1, 2018;
Emergency Amendment Eff. February 17, 2020;
Temporary Amendment Eff. April 24, 2020;
Amended Eff. April 1, 2021; July 1, 2020; 2020;
Amended Eff. November 1, 2024.