



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: March 2, 2020

TO: Rulemaking Interested Persons

FROM: Virginia Niehaus, Rulemaking Coordinator, Commission for Public Health and Director of Regulatory and Legal Affairs, Division of Public Health

RE: Notification of Proposed Permanent Amendment of 10A NCAC 41A .0101

Pursuant to G.S. § 150B-21.2, this memorandum serves as the required notice to interested persons that the North Carolina Commission for Public Health (CPH) is proposing to amend rule 10A NCAC 41A .0101. The proposed rule amends the communicable diseases and conditions reporting requirements to: (1) add Acute Flaccid Myelitis, Babesiosis, Varicella, and Interferon Gamma Release Assay testing; (2) re-list Zika; and (3) make technical changes related to nomenclature, timing of reporting, and scientific progress in laboratory testing and reporting. In addition, the text in italics adding a reporting requirement for novel coronavirus was adopted by CPH under emergency procedures on February 5, 2020 and effective on February 17, 2020, as well as proposed under temporary procedures. CPH has submitted notice of intent to amend this rule to the North Carolina Office of Administrative Hearings (OAH).

In accordance with G.S. § 150B-21.4, a fiscal note was prepared for the proposed permanent rule amendment and approved by CPH. The proposed changes will have an impact on state and local funds, but will not have a substantial economic impact. The fiscal note was approved by the North Carolina Office of State Budget and Management (OSBM) on December 13, 2019.

The notice of text that was published in today's edition of the North Carolina Register is attached to this memorandum and may be found on OAH's website at <https://www.oah.nc.gov/documents/nc-register>. The text of the proposed rules and the fiscal note may be found on CPH's website at <https://cph.publichealth.nc.gov/>.

A public hearing on these rules is scheduled for Monday, April 13, 2020 at 10:00 am in the Cardinal Conference Room, 5605 Six Forks Road, Raleigh, NC 27609, Building 3, 1st Floor.

CPH is accepting public comments on these rules from March 2, 2020 – May 1, 2020. You may submit comments by email to cphcomment@lists.ncmail.net or 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 proposed effective date of the rule is July 1, 2020.

If you have questions related to this memorandum, the proposed rule, or the fiscal note, please contact Dr. Jean-Marie Maillard, Medical Director, Communicable Disease Branch, Epidemiology Section, Division of Public Health at 919-733-3419.

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

LOCATION: 5605 Six Forks Road, Building 3, Raleigh, NC 27609
MAILING ADDRESS: 1931 Mail Service Center, Raleigh, NC 27699-1931
www.ncdhhs.gov • TEL: 919-707-5000 • FAX: 919-870-4829

AN EQUAL OPPORTUNITY / AFFIRMATIVE ACTION EMPLOYER

Attachment

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

TITLE 10A – DEPARTMENT OF HEALTH AND HUMAN SERVICES

Notice is hereby given in accordance with G.S. 150B-21.2 that the Commission for Public Health intends to amend the rule cited as 10A NCAC 41A .0101.

Link to agency website pursuant to G.S. 150B-19.1(c): <https://cph.publichealth.nc.gov/>

Proposed Effective Date: July 1, 2020

Public Hearing:

Date: April 13, 2020

Time: 10:00 a.m.

Location: Cardinal Conference Room, located at 5605 Six Forks Road, Raleigh, NC 27609

Reason for Proposed Action: *The surveillance and control of communicable diseases and conditions is an important part of protecting the public's health. The proposed rule amends the communicable diseases and conditions reporting requirements to: (1) Add Acute Flaccid Myelitis, Babesiosis, Varicella, and Interferon Gamma Release Assay testing; (2) re-list Zika; and (3) make technical changes related to nomenclature, timing of reporting, and scientific progress in laboratory testing and reporting. In addition, the text in italics adding a reporting requirement for novel coronavirus was adopted by the Commission for Public Health under emergency procedures on February 5, 2020 and effective on February 17, 2020 as well as proposed under temporary procedures.*

Comments may be submitted to: Virginia Niehaus, CPH Rulemaking Coordinator, 1931 Mail Service Center, Raleigh, NC 27699-1931; phone (919) 707-5006; email cphcomment@lists.ncmail.net

Comment period ends: May 1, 2020

Procedure for Subjecting a Proposed Rule to Legislative Review: If an objection is not resolved prior to the adoption of the rule, a person may also submit written objections to the Rules Review Commission after the adoption of the Rule. If the Rules Review Commission receives written and signed objections after the adoption of the Rule in accordance with G.S. 150B-21.3(b2) from 10 or more persons clearly requesting review by the legislature and the Rules Review Commission approves the rule, the rule will become effective as provided in G.S. 150B-21.3(b1). The Commission will receive written objections until 5:00 p.m. on the day following the day the Commission approves the rule. The Commission will receive those objections by mail, delivery service, hand delivery, or facsimile transmission. If you have any further questions concerning the submission of objections to the Commission, please call a Commission staff attorney at 919-431-3000.

Fiscal impact. Does any rule or combination of rules in this notice create an economic impact? Check all that apply.

- State funds affected
- Local funds affected
- Substantial economic impact (\geq \$1,000,000)
- Approved by OSBM
- No fiscal note required

CHAPTER 41 - EPIDEMIOLOGY HEALTH

SUBCHAPTER 41A - COMMUNICABLE DISEASE CONTROL

SECTION .0100 - COMMUNICABLE DISEASE CONTROL

10A NCAC 41A .0101 REPORTABLE DISEASES AND CONDITIONS

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

- (1) acquired immune deficiency syndrome (AIDS) - 24 hours;
- (2) acute flaccid myelitis – 7 days;
- (3) anaplasmosis – 7 days;
- (4)(2) anthrax - immediately;
- (5) arboviral infection, neuroinvasive – 7 days;
- (6) babesiosis – 7 days;
- (7)(3) botulism - immediately;
- (8)(4) brucellosis - 7 days;
- (9)(5) campylobacter infection - 24 hours;
- (10)(6) Candida auris - 24 hours;

- (11)(7) Carbapenem-Resistant Enterobacteriaceae (CRE) – 24 hours;
 (12)(8) chancroid - 24 hours;
 (13)(9) chikungunya virus infection - 24 hours;
 (14)(10) chlamydial infection (laboratory confirmed) - 7 days;
 (15)(11) cholera - 24 hours;
 (16)(12) Creutzfeldt-Jakob disease – 7 days;
 (17)(13) cryptosporidiosis – 24 hours;
 (18)(14) cyclosporiasis – 24 hours;
 (19)(15) dengue - 7 days;
 (20)(16) diphtheria - 24 hours;
 (21)(17) Escherichia coli, shiga toxin-producing infection - 24 hours;
 (22)(18) ehrlichiosis – 7 days;
 (19) ~~encephalitis, arboviral – 7 days;~~
 (23)(20) foodborne disease, including Clostridium perfringens, staphylococcal, Bacillus cereus, and other and unknown causes
 - 24 hours;
 (24)(21) gonorrhea - 24 hours;
 (25)(22) granuloma inguinale - 24 hours;
 (26)(23) Haemophilus influenzae, invasive disease - 24 hours;
 (27)(24) Hantavirus infection – 7 days;
 (28)(25) Hemolytic-uremic syndrome – 24 hours;
 (29)(26) Hemorrhagic fever virus infection – immediately;
 (30)(27) hepatitis A - 24 hours;
 (31)(28) hepatitis B - 24 hours;
 (32)(29) hepatitis B carriage - 7 days;
 (33)(30) hepatitis C, acute – 7 days;
 (34)(31) human immunodeficiency virus (HIV) infection confirmed - 24 hours;
 (35)(32) influenza virus infection causing death – 24 hours;
 (36)(33) legionellosis - 7 days;
 (37)(34) leprosy – 7 days;
 (38)(35) leptospirosis - 7 days;
 (39)(36) listeriosis – 24 hours;
 (40)(37) Lyme disease - 7 days;
 (41)(38) Lymphogranuloma venereum - 7 days;
 (42)(39) malaria - 7 days;
 (43)(40) measles (rubeola) - immediately; 24 hours;
 (44)(41) meningitis, pneumococcal - 7 days;
 (45)(42) meningococcal disease - 24 hours;
 (46)(43) Middle East respiratory syndrome (MERS) - 24 hours;
 (47)(44) monkeypox – 24 hours;
 (48)(45) mumps - 7 days;
 (49)(46) nongonococcal urethritis - 7 days;
 (50) novel coronavirus infection – immediately;
 (51)(47) novel influenza virus infection – immediately;
 (52)(48) plague - immediately;
 (53)(49) paralytic poliomyelitis - 24 hours;
 (54)(50) pelvic inflammatory disease – 7 days;
 (55)(51) psittacosis - 7 days;
 (56)(52) Q fever - 7 days;
 (57)(53) rabies, human - 24 hours;
 (54) ~~Rocky Mountain spotted fever – 7 days;~~
 (58)(55) rubella - 24 hours;
 (59)(56) rubella congenital syndrome - 7 days;
 (60)(57) salmonellosis - 24 hours;
 (61)(58) severe acute respiratory syndrome (SARS) – 24 hours;
 (62)(59) shigellosis - 24 hours;
 (63)(60) smallpox - immediately;
 (64) spotted fever rickettsiosis – 7 days;
 (65)(61) Staphylococcus aureus with reduced susceptibility to vancomycin – 24 hours;

- ~~(66)(62)~~ streptococcal infection, Group A, invasive disease - 7 days;
- ~~(67)(63)~~ syphilis - 24 hours;
- ~~(68)(64)~~ tetanus - 7 days;
- ~~(69)(65)~~ toxic shock syndrome - 7 days;
- ~~(70)(66)~~ trichinosis - 7 days;
- ~~(71)(67)~~ tuberculosis - 24 hours;
- ~~(72)(68)~~ tularemia – immediately;
- ~~(73)(69)~~ typhoid - 24 hours;
- ~~(74)(70)~~ typhoid carriage (*Salmonella typhi*) - 7 days;
- ~~(75)(71)~~ typhus, epidemic (louse-borne) - 7 days;
- ~~(76)(72)~~ vaccinia – 24 hours;
- ~~(77)~~ varicella – 24 hours;
- ~~(78)(73)~~ vibrio infection (other than cholera) – 24 hours;
- ~~(79)(74)~~ whooping cough – 24 hours; ~~and~~
- ~~(80)(75)~~ yellow fever – 7 days; ~~days, and~~
- ~~(81)~~ 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 or hemorrhagic fever virus.
 - ~~(C)(B)~~ Arthropod-borne virus (any type).
 - ~~(D)~~ Babesia spp., the cause of babesiosis.
 - ~~(E)(C)~~ *Bacillus anthracis*, the cause of anthrax.
 - ~~(F)(D)~~ *Bordetella pertussis*, the cause of whooping cough (pertussis).
 - ~~(G)(E)~~ *Borrelia burgdorferi*, the cause of Lyme disease (confirmed tests).
 - ~~(H)(F)~~ *Brucella* spp., the causes of brucellosis.
 - ~~(I)(G)~~ *Campylobacter* spp., the causes of campylobacteriosis.
 - ~~(J)(H)~~ *Candida auris*.
 - ~~(K)(I)~~ Carbapenem-Resistant Enterobacteriaceae (CRE).
 - ~~(L)(J)~~ *Chlamydia trachomatis*, the cause of genital chlamydial infection, conjunctivitis (adult and newborn) and pneumonia of newborns.
 - ~~(M)(K)~~ *Clostridium botulinum*, a cause of botulism.
 - ~~(N)(L)~~ *Clostridium tetani*, the cause of tetanus.
 - ~~(O)~~ *Coronavirus, novel human strain.*
 - ~~(P)(M)~~ *Corynebacterium diphtheriae*, the cause of diphtheria.
 - ~~(Q)(N)~~ *Coxiella burnetii*, the cause of Q fever.
 - ~~(R)(O)~~ *Cryptosporidium* spp., ~~parvum~~, the cause of human cryptosporidiosis.
 - ~~(S)(P)~~ *Cyclospora cayentanesis*, the cause of cyclosporiasis.
 - ~~(T)~~ Dengue virus.
 - ~~(U)(Q)~~ *Ehrlichia* spp., the causes of ehrlichiosis.
 - ~~(V)(R)~~ Shiga toxin-producing *Escherichia coli*, a cause of hemorrhagic colitis, hemolytic uremic syndrome, and thrombotic thrombocytopenic purpura.
 - ~~(W)(S)~~ *Francisella tularensis*, the cause of tularemia.
 - ~~(X)~~ Hepatitis A virus.
 - ~~(Y)(T)~~ Hepatitis B virus or any component thereof, such as hepatitis B surface antigen.
 - ~~(Z)(U)~~ Human Immunodeficiency Virus, the cause of AIDS.
 - ~~(AA)(V)~~ *Legionella* spp., the causes of legionellosis.
 - ~~(BB)(W)~~ *Leptospira* spp., the causes of leptospirosis.
 - ~~(CC)(X)~~ *Listeria monocytogenes*, the cause of listeriosis.
 - ~~(DD)~~ Measles virus.
 - ~~(EE)(Y)~~ Middle East respiratory syndrome virus.
 - ~~(FF)(Z)~~ Monkeypox.
 - ~~(GG)~~ Mumps virus.
 - ~~(HH)(AA)~~ *Mycobacterium leprae*, the cause of leprosy.
 - ~~(II)(BB)~~ *Plasmodium falciparum*, *P. malariae*, *P. ovale*, and *P. vivax*, the causes of malaria in humans.

- ~~(JJ)(CC)~~ Poliovirus (any), the cause of poliomyelitis.
~~(KK)(DD)~~ Rabies virus.
~~(LL)(EE)~~ Rickettsia spp., rickettsii, the cause of ~~Rocky Mountain spotted fever~~ rickettsiosis, fever.
~~(MM)(FF)~~ Rubella virus.
~~(NN)(GG)~~ Salmonella spp., the causes of salmonellosis.
~~(OO)(HH)~~ Shigella spp., the causes of shigellosis.
~~(PP)(II)~~ Smallpox virus, the cause of smallpox.
~~(QQ)(JJ)~~ Staphylococcus aureus with reduced susceptibility to vanomycin.
~~(RR)(KK)~~ Trichinella spiralis, the cause of trichinosis.
~~(SS)(LL)~~ Vaccinia virus.
~~(TT)~~ Varicella virus.
~~(UU)(MM)~~ Vibrio spp., the causes of cholera and other vibrioses.
~~(VV)(NN)~~ Yellow fever virus.
~~(WW)(OO)~~ Yersinia pestis, the cause of plague.
~~(XX)~~ Zika virus.

- (2) Isolation or other specific identification of the following organisms from normally sterile human body sites:
- (A) Group A Streptococcus pyogenes (group A streptococci).
(B) Haemophilus influenzae, serotype b.
(C) 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 ~~viruses~~ associated with neuroinvasive disease, meningitis or encephalitis in a human.
(ii) Anaplasma spp., the cause of anaplasmosis.
~~(iii)(ii)~~ Any hantavirus or hemorrhagic fever virus.
~~(iv)(iii)~~ Chlamydia psittaci, the cause of psittacosis.
(v) Chikungunya virus.
~~(vi)(iv)~~ Coxiella burnetii, the cause of Q fever.
~~(vii)(v)~~ Dengue virus.
~~(viii)(vi)~~ Ehrlichia spp., the causes of ehrlichiosis.
~~(ix)(vii)~~ Measles (rubeola) virus.
~~(x)(viii)~~ Mumps virus.
~~(xi)(ix)~~ Rickettsia rickettsii, the cause of Rocky Mountain spotted fever.
~~(xii)(x)~~ Rubella virus.
~~(xiii)~~ Varicella virus.
~~(xiv)(xi)~~ Yellow fever virus.
- (B) The presence of IgM serum antibodies to:
- (i) Any arthropod-borne virus associated with neuroinvasive disease.
(ii) Chikungunya virus.
~~(iii)(i)~~ Chlamydia psittaci.
~~(iv)~~ Dengue virus.
~~(v)(ii)~~ Hepatitis A virus.
~~(vi)(iii)~~ Hepatitis B virus core antigen.
~~(vii)~~ Mumps virus.
~~(viii)(iv)~~ Rubella virus.
~~(ix)(v)~~ Rubeola (measles) virus.
~~(x)(vi)~~ 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 CRE 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.*