

REQUEST FOR TECHNICAL CHANGE

AGENCY: Commission for Public Health

RULE CITATION: 10A NCAC 41A .0101

DEADLINE FOR RECEIPT: Thursday, September 8, 2016

NOTE WELL: *This request when viewed on computer extends 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 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. Approval of any rule is contingent upon making technical changes as set forth in G.S. 150B-21.10.

Complete box 10 on the Submission for Permanent Rule form

Page 3, lines 4 and 6, please track changes as published by striking through the "and" on line 4 and underlining "(74) Zika virus" and "— 24 hours" on line 6

Page 5, lines 14 thru 16, please make certain the line spacing is 1.5 lines per [26 NCAC 02C .0108\(1\)\(g\)](#)

Page 5, line 15, add "the following" between "including" and the colon

Page 5, line 16, please track changes as published. Specifically, there was a comma published after "ratio)" Please add the comma into the text submitted for review

Page 5, lines 16, 17, and 18, replace the commas at the end of each clause with a semicolon. Please track the changes since publication in accordance with [26 NCAC 02C .0405\(b\)\(2\)](#)

Page 5, line 18, add an "and" after the semicolon

Page 2, line 38, replace the colon after "2016" with a semicolon. As this was not published, there is no need to track the change. Simply replace the colon with the semicolon.

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

Abigail M. Hammond
Commission Counsel

Date submitted to agency: Wednesday, August 24, 2016

1 10A NCAC 41A .0101 is amended with changes as published in 30:23 NCR 2435-2437 as follows:

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3 **10A NCAC 41A .0101 REPORTABLE DISEASES AND CONDITIONS**

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

- 6 (1) acquired immune deficiency syndrome (AIDS) - 24 hours;
- 7 (2) anthrax - immediately;
- 8 (3) botulism - immediately;
- 9 (4) brucellosis - 7 days;
- 10 (5) campylobacter infection - 24 hours;
- 11 (6) chancroid - 24 hours;
- 12 (7) chikungunya virus infection - 24 hours;
- 13 (8) chlamydial infection (laboratory confirmed) - 7 days;
- 14 (9) cholera - 24 hours;
- 15 (10) Creutzfeldt-Jakob disease – 7 days;
- 16 (11) cryptosporidiosis – 24 hours;
- 17 (12) cyclosporiasis – 24 hours;
- 18 (13) dengue - 7 days;
- 19 (14) diphtheria - 24 hours;
- 20 (15) Escherichia coli, shiga toxin-producing - 24 hours;
- 21 (16) ehrlichiosis – 7 days;
- 22 (17) encephalitis, arboviral - 7 days;
- 23 (18) foodborne disease, including Clostridium perfringens, staphylococcal, Bacillus cereus, and other
24 and unknown causes - 24 hours;
- 25 (19) gonorrhea - 24 hours;
- 26 (20) granuloma inguinale - 24 hours;
- 27 (21) Haemophilus influenzae, invasive disease - 24 hours;
- 28 (22) Hantavirus infection – 7 days;
- 29 (23) Hemolytic-uremic syndrome – 24 hours;
- 30 (24) Hemorrhagic fever virus infection – immediately;
- 31 (25) hepatitis A - 24 hours;
- 32 (26) hepatitis B - 24 hours;
- 33 (27) hepatitis B carriage - 7 days;
- 34 (28) hepatitis C, acute – 7 days;
- 35 (29) human immunodeficiency virus (HIV) infection confirmed - 24 hours;
- 36 (30) influenza virus infection causing death – 24 hours;
- 37 (31) legionellosis - 7 days;

- 1 (32) leprosy – 7 days;
- 2 (33) leptospirosis - 7 days;
- 3 (34) listeriosis – 24 hours;
- 4 (35) Lyme disease - 7 days;
- 5 (36) lymphogranuloma venereum - 7 days;
- 6 (37) malaria - 7 days;
- 7 (38) measles (rubeola) - 24 hours;
- 8 (39) meningitis, pneumococcal - 7 days;
- 9 (40) meningococcal disease - 24 hours;
- 10 (41) Middle East respiratory syndrome (MERS) - 24 hours;
- 11 (42) monkeypox – 24 hours;
- 12 (43) mumps - 7 days;
- 13 (44) nongonococcal urethritis - 7 days;
- 14 (45) novel influenza virus infection – immediately;
- 15 (46) plague - immediately;
- 16 (47) paralytic poliomyelitis - 24 hours;
- 17 (48) pelvic inflammatory disease – 7 days;
- 18 (49) psittacosis - 7 days;
- 19 (50) Q fever - 7 days;
- 20 (51) rabies, human - 24 hours;
- 21 (52) Rocky Mountain spotted fever - 7 days;
- 22 (53) rubella - 24 hours;
- 23 (54) rubella congenital syndrome - 7 days;
- 24 (55) salmonellosis - 24 hours;
- 25 (56) severe acute respiratory syndrome (SARS) – 24 hours;
- 26 (57) shigellosis - 24 hours;
- 27 (58) smallpox - immediately;
- 28 (59) Staphylococcus aureus with reduced susceptibility to vancomycin – 24 hours;
- 29 (60) streptococcal infection, Group A, invasive disease - 7 days;
- 30 (61) syphilis - 24 hours;
- 31 (62) tetanus - 7 days;
- 32 (63) toxic shock syndrome - 7 days;
- 33 (64) trichinosis - 7 days;
- 34 (65) tuberculosis - 24 hours;
- 35 (66) tularemia – immediately;
- 36 (67) typhoid - 24 hours;
- 37 (68) typhoid carriage (Salmonella typhi) - 7 days;

- (69) typhus, epidemic (louse-borne) - 7 days;
- (70) vaccinia – 24 hours;
- (71) vibrio infection (other than cholera) – 24 hours;
- (72) whooping cough – 24 hours; and
- (73) yellow fever - 7 ~~days~~ days; and
- (74) Zika virus infection – 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:

- (1) Isolation or other specific identification of the following organisms or their products from human clinical specimens:
 - (A) Any hantavirus or hemorrhagic fever virus.
 - (B) Arthropod-borne virus (any type).
 - (C) Bacillus anthracis, the cause of anthrax.
 - (D) Bordetella pertussis, the cause of whooping cough (pertussis).
 - (E) Borrelia burgdorferi, the cause of Lyme disease (confirmed tests).
 - (F) Brucella spp., the causes of brucellosis.
 - (G) Campylobacter spp., the causes of campylobacteriosis.
 - (H) Chlamydia trachomatis, the cause of genital chlamydial infection, conjunctivitis (adult and newborn) and pneumonia of newborns.
 - (I) Clostridium botulinum, a cause of botulism.
 - (J) Clostridium tetani, the cause of tetanus.
 - (K) Corynebacterium diphtheriae, the cause of diphtheria.
 - (L) Coxiella burnetii, the cause of Q fever.
 - (M) Cryptosporidium parvum, the cause of human cryptosporidiosis.
 - (N) Cyclospora cayetanesis, the cause of cyclosporiasis.
 - (O) Ehrlichia spp., the causes of ehrlichiosis.
 - (P) Shiga toxin-producing Escherichia coli, a cause of hemorrhagic colitis, hemolytic uremic syndrome, and thrombotic thrombocytopenic purpura.
 - (Q) Francisella tularensis, the cause of tularemia.
 - (R) Hepatitis B virus or any component thereof, such as hepatitis B surface antigen.

- (S) Human Immunodeficiency Virus, the cause of AIDS.
 - (T) *Legionella* spp., the causes of legionellosis.
 - (U) *Leptospira* spp., the causes of leptospirosis.
 - (V) *Listeria monocytogenes*, the cause of listeriosis.
 - (W) Middle East respiratory syndrome virus.
 - (X) Monkeypox.
 - (Y) *Mycobacterium leprae*, the cause of leprosy.
 - (Z) *Plasmodium falciparum*, *P. malariae*, *P. ovale*, and *P. vivax*, the causes of malaria in humans.
 - (AA) Poliovirus (any), the cause of poliomyelitis.
 - (BB) Rabies virus.
 - (CC) *Rickettsia rickettsii*, the cause of Rocky Mountain spotted fever.
 - (DD) Rubella virus.
 - (EE) *Salmonella* spp., the causes of salmonellosis.
 - (FF) *Shigella* spp., the causes of shigellosis.
 - (GG) Smallpox virus, the cause of smallpox.
 - (HH) *Staphylococcus aureus* with reduced susceptibility to vanomycin.
 - (II) *Trichinella spiralis*, the cause of trichinosis.
 - (JJ) Vaccinia virus.
 - (KK) *Vibrio* spp., the causes of cholera and other vibrioses.
 - (LL) Yellow fever virus.
 - (MM) *Yersinia pestis*, the cause of plague.
- (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 viruses associated with meningitis or encephalitis in a human.
 - (ii) Any hantavirus or hemorrhagic fever virus.
 - (iii) *Chlamydia psittaci*, the cause of psittacosis.
 - (iv) *Coxiella burnetii*, the cause of Q fever.
 - (v) Dengue virus.
 - (vi) *Ehrlichia* spp., the causes of ehrlichiosis.
 - (vii) Measles (rubeola) virus.

- (viii) Mumps virus.
 - (ix) *Rickettsia rickettsii*, the cause of Rocky Mountain spotted fever.
 - (x) Rubella virus.
 - (xi) Yellow fever virus.
- (B) The presence of IgM serum antibodies to:
- (i) *Chlamydia psittaci*.
 - (ii) Hepatitis A virus.
 - (iii) Hepatitis B virus core antigen.
 - (iv) Rubella virus.
 - (v) Rubeola (measles) virus.
 - (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.
- (d) Laboratories utilizing electronic laboratory reporting (ELR) shall report all positive laboratory results from tests used to diagnosis hepatitis C infection, including:
- (1) Hepatitis C virus antibody tests (including the test specific signal to cut-off (s/c) ratio)
 - (2) Hepatitis C nucleic acid tests.
 - (3) Hepatitis C antigen(s) tests.
 - (4) Hepatitis C genotypic tests.
- 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~~ 2016:*

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Amended Eff 10 1, 2016.