NC DEPARTMENT OF HEALTH AND HUMAN SERVICES

Commission for Public Health

ROY COOPER • Governor
KODY H. KINSLEY • Secretary
MARK T. BENTON • Chief Deputy Secretary for Health
SUSAN KANSAGRA • Assistant Secretary for Public Health
Division of Public Health

MEMORANDUM

DATE: June 3, 2024

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 Rule Amendment: 10A NCAC 41A .0101

Pursuant to G.S. 150B-21.2, this memorandum serves as the required notice to interested persons that the Commission for Public Health (CPH) is proposing to amend the communicable diseases and conditions reporting requirements in rule 10A NCAC 41A .0101 to: (1) expand from reporting of carbapenem-resistant enterobacteriaceae (CRE) to the reporting of all carbapenemase-producing organisms (CPO); (2) add a reporting requirement for invasive Cronobacter infections in individuals less than 12 months of age; and (3) make other technical updates to rule language. CPH has submitted notice of its intent to amend this rule to the NC Office of Administrative Hearings (OAH).

In accordance with G.S. 150B-21.4, a fiscal note was prepared for the proposed rule and approved by CPH. The proposed rule is expected to have an impact on state and local funds, but is not expected to have a substantial economic impact. The fiscal note was approved by the NC Office of State Budget and Management (OSBM) on April 18, 2024.

The notice of text that was published in today's edition of the NC Register is attached to this memorandum and may be found on OAH's website at https://www.oah.nc.gov/rules-division/north-carolina-register. The text of the proposed rule and fiscal note may be found on the CPH's website at https://cph.dph.ncdhhs.gov/.

A public hearing on the proposed rule is scheduled for Thursday, July 11, 2024 at 10:00 a.m. The public hearing will be held by teleconference. You may participate in the public hearing by dialing 919-715-0769. No access code is required.

CPH is accepting public comments on the proposed rule from June 3, 2024 through August 2, 2024. 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 proposed effective date of the rule amendment is October 1, 2024.

Should you have questions related to this memorandum, the proposed rule, or the fiscal note, please contact Erica Wilson, Medical Director, Medical Consultation Unit, Communicable Disease Branch, Epidemiology Section, Division of Public Health at (919) 546-1682.

Attachment

cc: Dr. Ronald May, Chair, Commission for Public Health
Dr. Susan Kansagra, Assistant Secretary for Public Health, Division of Public Health
Dr. Zack Moore, Epidemiology Section Chief, Division of Public Health
Dr. Erica Wilson, Medical Director, Medical Consultation Unit, Communicable Disease Branch, Epidemiology Section, 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.dph.ncdhhs.gov/*

Proposed Effective Date: *October 1, 2024*

Public Hearing:
Date: *July 11, 2024*
Time: *10:00 a.m.*
Location: *This public hearing will be held by teleconference at (919) 715-0769 (no access code required).*

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) expand from reporting of carbapenem-resistant enterobacteriaceae (CRE) to the reporting of all carbapenemase-producing organisms (CPO); (2) add a reporting requirement for invasive Cronobacter infections in individuals less than 12 months of age; and (3) make other technical updates to rule language.*

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

Comment period ends: *August 2, 2024*

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 a written objection to the Rules Review Commission. 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 letters via U.S. Mail, private courier service, or hand delivery to 1711 New Hope Church Road, Raleigh, North Carolina, or via email to oah.rules@oah.nc.gov. If you have any further questions concerning the submission of objections to the Commission, please review 26 NCAC 05 .0110 or call a Commission staff attorney at 984-236-1850.

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 (>= $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) anthrax ‑ immediately;
(5) arboviral infection, neuroinvasive – 7 days;
(6) babesiosis – 7 days;
(7) botulism ‑ immediately;
(8) brucellosis ‑ 7 days;
(9) campylobacter infection ‑ 24 hours;
(10) Candida auris - 24 hours;
(11) ~~Carbapenem-Resistant Enterobacteriaceae (CRE)~~ Carbapenemase-producing organisms (CPO) – 24 hours;

(12) chancroid – 24 hours;
(13) chikungunya virus infection – 24 hours;
(14) chlamydial infection (laboratory confirmed) – 7 days;
(15) cholera – 24 hours;
(16) Creutzfeldt-Jakob disease – 7 days;
(17) cronobacter infection, invasive, in individuals less than twelve months of age – 24 hours;
(18)~~(17)~~ cryptosporidiosis – 24 hours;
(19)~~(18)~~ cyclosporiasis – 24 hours;
(20)~~(19)~~ dengue – 7 days;
(21)~~(20)~~ diphtheria – 24 hours;
(22)~~(21)~~ Escherichia coli, shiga toxin-producing infection – 24 hours;
(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.
~~(A)~~(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 ~~CRE~~ 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.

~~(c) 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.