Fiscal Note for Permanent Rule Changes for North Carolina Division of Public Health
Requires OSBM Review- Seeking Fast-Track Approval

Agency: Dept. Of Health and Human Services, Division of Public Health, Epidemiology Section, Communicable Disease Branch
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Rule Citations:
10A NCAC 41A .0101 REPORTABLE DISEASES AND CONDITIONS

Purpose of Rule Changes: *10A NCAC 41A .0101 - Reportable Diseases and Conditions*
Make permanent the temporary rule adding Zika to Reportable Diseases and Conditions

Relevant Statutes: GS 130A-134; 130A-135; 130A-139; 130A-141

State Impact: Yes
Local Impact: Yes
Substantial Economic Impact: No

Reason for Proposed Amendment:
Zika virus infection was first characterized in Africa. In 2015, sustained transmission was identified in Brazil and subsequent local transmission has been identified in numerous countries in South and Central America and the Caribbean. Travel associated cases have been identified in continental US. Local transmission in the continental United States is possible based on previous experience with Dengue and Chikungunya. Rapid case identification and application 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 or confirmed so that appropriate control measures can be implemented to prevent further spread. For this reason, the State Health Director issued a temporary order pursuant to G.S. 130A-141.1 requiring immediate reporting of either condition effective February 1st, 2016. An emergency rule was implemented effective on March 1, 2016, which will be followed by a temporary rule that will be effective on June 20, 2016. This proposed amendment replaces the temporary rule to require ongoing reporting of Zika virus infection.

Reason for Fiscal Note
The rule change to require reporting for Zika does not in of itself result in a significant impact. The NC State Laboratory for Public Health (SLPH) and the Centers for Disease Control and Prevention (CDC) are the only facilities certified to conduct testing for Zika, and, as a standard of medical care, healthcare providers must send samples to the SLPH when conditions indicating Zika are present in a patient. Submission of test samples would occur without the rule. Test results from the SLPH and CDC are automatically reported to communicable disease staff, and this may happen even if the proposed rule were not in place.

Currently, testing for this disease is not available at commercial laboratories. However, as with other emerging arboviral diseases, such as West Nile virus and Chikungunya, it is anticipated that testing at commercial laboratories will become available. Without required reporting, the communicable disease branch would not receive test reports from these other laboratories. As such, the situation regarding Zika does warrant a fiscal note.

The impact from the required reporting is on communicable disease staff at local health departments to expend time receiving reports for Zika from healthcare providers. State communicable disease staff time is required to provide follow-up consultation regarding these test results, and on the SLPH for performing the tests. Further, there is a minimal impact on healthcare providers to report to communicable disease staff. All impacts are minimal opportunity costs involving existing state, local, and private sector staff. No additional expenditures are required.

While the estimated costs of Zika virus reporting are relatively small, the potential benefits may be significant if this reporting requirement manages to prevent cases of the Zika virus. Aside from avoiding the treatment cost and lost time

from work for the patient, avoiding severe fetal brain defects, like microcephaly, which have been linked to the infections with the Zika virus during pregnancy would results in substantial health benefits.[1],[2] Microcephaly is a medical condition in which the brain does not develop properly resulting in a smaller than normal head. Often people with the disorder have an intellectual disability, poor motor function, poor speech, abnormal facial features, and seizures.[3] The association with microcephaly has led the WHO to declare Zika a public health emergency.[4] The potential to avoid any costs related to dealing with the effects of microcephaly and other defects, including costs of therapy and necessary health treatments, as well as the lost time from work for the parents would far outweigh the costs of the Zika reporting requirements that are presented below.

Figure 1 shows the total estimated impact of this rule change. The estimates in the figure are based on the total of 89 reports involving Chikungunya during calendar year 2014 in North Carolina. Chikungunya is used as a proxy for the Zika virus since there is little data on Zika, and Chikungunya co-circulates with Zika and is transmitted by the same types of mosquitoes. Therefore, it is likely that they would have similar patterns of transmission and impact.

The impact on the county agencies was estimated based on the total compensation of $40 for a Public Health Nurse II, which includes a salary of $19.6 per hour obtained from the Public Health Nursing Program in the NC Division of Public Health, as well as an assumption that the benefits package (health, retirement, paid leave, etc.) is similar to what state employees receive and it is about 52% of their wage.[5] The impact on the state agency was estimated based on the mean hourly wage for a State Epidemiologist of $59 and for a Medical Laboratory Technician of $27.5, as well as the assumption of the benefits package being about 41.2% and 46% of the wage, respectively.[6] The impact on the private sector was estimated based on the amount of time estimated for a healthcare provider staff (usually an RN) to fax medical information to the local health department and/or answer medical questions from the local health department. The cost for the time of the healthcare professional is based on their wage of $29, which was obtained from the 2015 State Occupational Employment and Wage Estimates in NC published by the Bureau of Labor Statistics for Registered Nurses[7] and an assumption of benefits of 42%.[8]

The analysis assumes that the annual impact presented in the figure below would stay relatively constant over the next few years.

[1] US Centers for Disease Control and Prevention. About the Zika Virus Disease. http://www.cdc.gov/zika/about/index.html
[2] Mlakar, Jermej et. Al. "Zika Virus Associated with Microcephaly." March 10, 2016. The New England Journal of Medicine. http://www.nejm.org/doi/full/10.1056/NEJMoa1600651#t=article
[3] Boston Children's Hospital. Treatments for Microcephaly in Children. http://www.childrenshospital.org/conditions-and-treatments/conditions/m/microcephaly/treatments
[4] WHO. WHO Director-General briefs the media on the Zika situation. March 2016. WHO Director-General briefs the media on the Zika situation http://www.who.int/mediacentre/news/statements/2016/zika-update-3-16/en/
[5] NC Office of State Human Resources. 2015 Compensation and Benefits Report. http://s3.amazonaws.com/oshr.ncgovstaging.fayze2.com/s3fs-public/migrated_files/Guide/CompWebSite/2015%20CompBenefits%20Report%20_finalpdf.pdf
[6] NC Office of State Human Resources. Total Compensation Calculator. http://oshr.nc.gov/state-employee-resources/classification-compensation/total-compensation-calculator
[7] Bureau of Labor Statistics. May 2015 State Occupational Employment and Wage Estimates North Carolina. http://www.bls.gov/oes/current/oes_nc.htm
[8] Bureau of Labor Statistics. Employer costs per hour worked for employee compensation and costs as a percent of total compensation: Private industry workers, by major industry group, December 2015 http://www.bls.gov/news.release/ecec.t06.htm

Figure 1

NC DPH Permanent Reporting of Zika

Impact Analysis

Projected Annual Cost[1]

A. Annual Impact on Private Sector (Based on 2014 Chikungunya Events Reported)

# Estimated Events Reported	Total Hours per Event Reported	Hourly Salary of Private Sector Registered Nurse [2]	Total Cost to Private Sector
89	0.5	$41	**$1,800**

B. Annual Impact on State Agency: Division of Public Health, Epidemiology Section, Communicable Disease Branch (Based on 2014 Chikungunya Events Reported)

# Estimated Events Reported	Total Hours per Event Reported	Hourly Salary of State Epidemiologist	Cost to State Agency
89	1	$84	$7,500
# Estimated Events Reported	**Total Hours per Event Reported**	**Hourly Salary of Medical Laboratory Technician**	**Cost to State Agency**
89	1	$40	$3,600
			Total Cost to State
			$11,100

C. Annual Impact on County Agencies: Local Health Department Communicable Disease Branch
D. (Based on 20014 Events Reported)

# Events Reported	Total Hours per Event Reported	Hourly Total Compensation of Public Health Nurse II	Total Cost to County Agencies
89	1	$30	**$2,650**

Total Annual Estimated Economic Impact

Private Costs Sector	$1,800
State Gov't Costs	$11,100
Local Gov't	$2,700
Total Costs	**$15,600**

[1] Estimates were rounded to the nearest hundred dollars.

Appendix A:

CHAPTER 41 - HEALTH: EPIDEMIOLOGY

SUBCHAPTER 41A - COMMUNICABLE DISEASE CONTROL

SECTION .0100 - REPORTING OF COMMUNICABLE DISEASES

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) anthrax - immediately;
(3) botulism - immediately;
(4) brucellosis - 7 days;
(5) campylobacter infection - 24 hours;
(6) chancroid - 24 hours;
(7) chikungunya virus infection - 24 hours;
(8) chlamydial infection (laboratory confirmed) - 7 days;
(9) cholera - 24 hours;
(10) Creutzfeldt-Jakob disease – 7 days;
(11) cryptosporidiosis – 24 hours;
(12) cyclosporiasis – 24 hours;
(13) dengue - 7 days;
(14) diphtheria - 24 hours;
(15) Escherichia coli, shiga toxin-producing - 24 hours;
(16) ehrlichiosis – 7 days;
(17) encephalitis, arboviral - 7 days;
(18) foodborne disease, including Clostridium perfringens, staphylococcal, Bacillus cereus, and other and unknown causes - 24 hours;
(19) gonorrhea - 24 hours;
(20) granuloma inguinale - 24 hours;
(21) Haemophilus influenzae, invasive disease - 24 hours;
(22) Hantavirus infection – 7 days;
(23) Hemolytic-uremic syndrome – 24 hours;
(24) Hemorrhagic fever virus infection – immediately;
(25) hepatitis A - 24 hours;
(26) hepatitis B - 24 hours;
(27) hepatitis B carriage - 7 days;
(28) hepatitis C, acute – 7 days;
(29) human immunodeficiency virus (HIV) infection confirmed - 24 hours;
(30) influenza virus infection causing death – 24 hours;
(31) legionellosis - 7 days;
(32) leprosy – 7 days;
(33) leptospirosis - 7 days;
(34) listeriosis – 24 hours;
(35) Lyme disease - 7 days;
(36) lymphogranuloma venereum - 7 days;
(37) malaria - 7 days;
(38) measles (rubeola) - 24 hours;
(39) meningitis, pneumococcal - 7 days;
(40) meningococcal disease - 24 hours;
(41) Middle East respiratory syndrome (MERS) - 24 hours;
(42) monkeypox – 24 hours;
(43) mumps - 7 days;
(44) nongonococcal urethritis - 7 days;
(45) novel influenza virus infection – immediately;
(46) plague - immediately;
(47) paralytic poliomyelitis - 24 hours;
(48) pelvic inflammatory disease – 7 days;

(49) psittacosis - 7 days;
(50) Q fever - 7 days;
(51) rabies, human - 24 hours;
(52) Rocky Mountain spotted fever - 7 days;
(53) rubella - 24 hours;
(54) rubella congenital syndrome - 7 days;
(55) salmonellosis - 24 hours;
(56) severe acute respiratory syndrome (SARS) – 24 hours;
(57) shigellosis - 24 hours;
(58) smallpox - immediately;
(59) Staphylococcus aureus with reduced susceptibility to vancomycin – 24 hours;
(60) streptococcal infection, Group A, invasive disease - 7 days;
(61) syphilis - 24 hours;
(62) tetanus - 7 days;
(63) toxic shock syndrome - 7 days;
(64) trichinosis - 7 days;
(65) tuberculosis - 24 hours;
(66) tularemia – immediately;
(67) typhoid - 24 hours;
(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;
(73) yellow fever - 7 days; and
(74) 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:

(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.

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.