

Fiscal Note for Permanent Rule Changes for North Carolina Division of Public Health

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: Add influenza-associated deaths in persons 18 years of age and older to the list of reportable diseases and conditions (i.e., remove “in persons less than 18 years of age” from condition number 29, “influenza virus infection causing death in persons less than 18 years of age”).

Note: This rule amendment was originally approved by OSBM on August 27, 2010 and became effective April 1, 2011. However, the agency needs to re-adopt this amendment since a subsequent change to the rule mistakenly re-set the requirement for the reporting of influenza-associated deaths back to the version that existed prior to April 2011.

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

State Impact: Yes

Local Impact: Yes

Substantial Economic Impact: No

Significant Rule Change: No

Reason for Fiscal Note

This rule change (see proposed rule change in Appendix) requires a fiscal note because it would require communicable disease staff at local health departments to expend time investigating and reporting influenza-associated deaths in persons 18 years of age and older. Time could also be required for physicians and other health care workers to report these events to their local health departments. The aggregate annual impact is not expected to be substantial. In a survey conducted by the Communicable Disease Branch with the local health departments, the respondents reported local health department staff time required for investigating and reporting these cases was not excessive. Also, Branch staff estimates that the health care worker time required to report these events to the local health departments is minimal. However, the impact is projected based on 65 such cases that were reported during the couple of influenza seasons; in total, the fiscal impact during the one-year period when the temporary rule has been in place is below the \$1 million threshold to be considered as substantial.

North Carolina Communicable Disease Branch

The Communicable Disease Branch is located within the Epidemiology Section of the Division of Public Health. The goal of the Communicable Disease Branch is to conduct surveillance activities for communicable diseases, including HIV and other STDs, and other diseases reportable under NC law, and to protect the health of the citizens of North Carolina through prevention and control of those diseases. Branch staff reviews case report data and assists local health directors and others investigate disease cases and outbreaks, determine appropriate controls measures to help prevent disease transmission, and ensure that these control measures are applied. The Branch is also responsible for monitoring health data from hospital emergency departments, poison center calls, ambulance data, and other sources to detect diseases that may result from terrorism and for providing situational awareness during disease outbreaks, natural disasters, or man-made disasters. In addition, the AIDS care component of the Branch ensures that HIV/AIDS-infected individuals are able to access a continuum of care services, including case management, medical and dental care, complicated and expensive medications regimens, housing, and a full range of ancillary services.

Rule 10A NCAC 41A .0101- REPORTABLE DISEASES AND CONDITIONS

When the 2009 H1N1 influenza pandemic was first identified, the North Carolina Division of Public Health requested local health departments to voluntarily report all confirmed and probable 2009 H1N1 influenza cases, including fatal cases. This requirement ended on September 23, 2009. The State Health Director then issued a temporary order pursuant to G.S. 130A-141.1 requiring physicians licensed who practice medicine in this State to report all influenza-associated deaths in persons 18 years of age or older. (Influenza-associated deaths in persons less than 18 years of age were made reportable in 2004.) The reporting of all influenza deaths was deemed critical to influenza surveillance efforts and was critical in helping public health officials identify and characterize the groups who are at highest risk so that they could design appropriate public health interventions to help save lives. The reporting required pursuant to the order was valid for only 90 days. The temporary order was subsequently adopted by the Rules Review Commission as a temporary rule and expired on September 11, 2010. The temporary rule was replaced with a permanent rule that became effective on April 1, 2011. A subsequent change to the rule, however, mistakenly re-set the requirement for the reporting of influenza-associated deaths back to the version that existed prior to April 2011, prompting the need to readopt the rule to include the requirement for reporting influenza death for those 18 or older.

Reporting of all influenza-associated deaths continues to be a critical component of influenza surveillance in the state. Influenza is a vaccine-preventable disease, and this reporting allows DPH to monitor the effectiveness of our prevention and control strategies. Specifically, reporting during the one-year period covered by the temporary order and rule helped identify conditions that confer a higher risk for dying from influenza, including pregnancy and certain medical conditions such as asthma, heart disease, and diabetes. This reporting also identified certain demographic features associated with increased risk of dying from influenza, including Black race and Hispanic ethnicity. These findings allowed DPH and public health partners to target immunization and education campaigns to prevent unnecessary deaths. Finally, we learned that none of the persons whose deaths were reported had received H1N1 vaccine, and ¼ had never been treated with antiviral medications - both important findings for public health communications with physicians. The economic impact during this period was below the \$1 million threshold for being considered as having a substantial economic impact.

Table 1 below shows the total estimated fiscal impact of this rule change. The impacts are based on the average number of reported influenza-related deaths in the 2012-13 and 2013-14 (to date) seasons, i.e. 64. The impact for private sector and the local health departments is likely overestimated since there were 59 and 69 cases total recorded in 2012-13 and 2013-14, respectively; there is no available data to apportion the numbers of cases to each type of institution. The fiscal impact on the county agencies was estimated based on the 2014 mean hourly wage of \$23.95 for a Public Health Nurse, obtained from the University of North Carolina School of Government Country Salary Index. The fiscal impact on the private sector was estimated based on the amount of time infection control personnel or staff in nonhospital medical facilities (usually a Registered Nurse) may take to fax medical information and/or answer medical questions from the local health department. The hourly wage for this position, \$28.25, was obtained from the 2012 State Occupational Employment and Wage Estimates in NC published by the Bureau of Labor Statistics for Registered Nurses. The impact estimate also employs an hourly salary rate of \$57 for the State Epidemiologist in the Communicable Diseases Branch. All labor cost estimates presented in Table 1 include benefits in additional to the salary, estimated at a third of the salary.

Based on the calculation seen in Table 1, the estimated economic impact during this past influenza season was below the \$1 million threshold for being considered as having a substantial economic impact. The Communicable Disease Branch cannot forecast the number of deaths for future influenza seasons. However, even if the volume were to increase dramatically, we project that the fiscal impact of permanent reporting of influenza-associated deaths would remain below the substantial economic impact threshold.

Table 1

NC DPH Permanent Reporting of Flu-Associated Deaths			
Impact Analysis			
Impact on Private Sector (Based on Influenza Season Volume between 2012 and 2014)			
# Adult Influenza-Associated Deaths ¹	Total Hours per Event Reported	Hourly Compensation of Registered Nurse ²	Total Cost to Private Sector
64	0.5	\$37.67	\$1,205
Impact on State Agency: Division of Public Health, Epidemiology Section, Communicable Disease Branch (Based on Influenza Season Volume between 2012 and 2014)			
# Adult Influenza-Associated Deaths	Total Hours per Event Reported	Hourly Compensation of State Epidemiologist	Total Cost to State Agency
64	2	\$75.69	\$9,689
Impact on State Agency: Division of MH/DD/SAS, State Operated Healthcare Facilities (Based on 2009-10 Influenza Season Volume)³			
# Adult Influenza-Associated Deaths	Total Hours per Event Reported	Hourly Compensation of Registered Nurse ²	Total Cost to State Agency
1	0.5	\$37.67	\$19
Impact on County Agencies: Local Health Department Communicable Disease Branch (Based on Influenza Season Volume between 2012 and 2014)			
# Adult Influenza-Associated Deaths	Total Hours per Event Reported	Hourly Compensation of Public Health Nurse at LHD ⁴	Total Cost to County Agencies
64	5	\$31.93	\$10,218
Total Annual Estimated Economic Impact			
Increased Private Sector Expenses	\$1,205		
Increase State Gov't Expenses	\$9,707		
Increased Local Gov't Expenses	\$10,218		
Total Costs	\$21,131		
¹ While changes in circulating flu strains and public health interventions might cause higher or lower numbers of deaths to occur, it is difficult to forecast these changes in advance. ² Source: Bureau of Labor Statistics (http://www.bls.gov/oes/current/oes_nc.htm) ³ Flu Deaths occurring in NC state operated facilities are reportable. In the 2009-10 flu season, one death was reported from a state facility and the impact was calculated based on same rate as for the private sector (a Registered Nurse hourly rate times ½ hour effort to report). ⁴ Source: UNC School of Government (http://sogpubs.unc.edu/electronicversions/pdfs/cosal2014/nurse.pdf)			

APPENDIX

10A NCAC 41A .0101 is proposed for amendment as follows:

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) chlamydial infection (laboratory confirmed) - 7 days;
- (8) cholera - 24 hours;
- (9) Creutzfeldt-Jakob disease – 7 days;
- (10) cryptosporidiosis – 24 hours;
- (11) cyclosporiasis – 24 hours;
- (12) dengue - 7 days;
- (13) diphtheria - 24 hours;
- (14) Escherichia coli, shiga toxin-producing - 24 hours;
- (15) ehrlichiosis – 7 days;
- (16) encephalitis, arboviral - 7 days;
- (17) foodborne disease, including Clostridium perfringens, staphylococcal, Bacillus cereus, and other and unknown causes - 24 hours;
- (18) gonorrhea - 24 hours;
- (19) granuloma inguinale - 24 hours;
- (20) Haemophilus influenzae, invasive disease - 24 hours;
- (21) Hantavirus infection – 7 days;
- (22) Hemolytic-uremic syndrome – 24 hours;
- (23) Hemorrhagic fever virus infection – immediately;
- (24) hepatitis A - 24 hours;
- (25) hepatitis B - 24 hours;
- (26) hepatitis B carriage - 7 days;
- (27) hepatitis C, acute – 7 days;
- (28) human immunodeficiency virus (HIV) infection confirmed - 24 hours;
- (29) influenza virus infection causing death ~~in persons less than 18 years of age~~ – 24 hours;
- (30) legionellosis - 7 days;
- (31) leprosy – 7 days;
- (32) leptospirosis - 7 days;
- (33) listeriosis – 24 hours;
- (34) Lyme disease - 7 days;

- (35) lymphogranuloma venereum - 7 days;
- (36) malaria - 7 days;
- (37) measles (rubeola) - 24 hours;
- (38) meningitis, pneumococcal - 7 days;
- (39) meningococcal disease - 24 hours;
- (40) monkeypox – 24 hours;
- (41) mumps - 7 days;
- (42) nongonococcal urethritis - 7 days;
- (43) novel influenza virus infection – immediately;
- (44) plague - immediately;
- (45) paralytic poliomyelitis - 24 hours;
- (46) pelvic inflammatory disease – 7 days;
- (47) psittacosis - 7 days;
- (48) Q fever - 7 days;
- (49) rabies, human - 24 hours;
- (50) Rocky Mountain spotted fever - 7 days;
- (51) rubella - 24 hours;
- (52) rubella congenital syndrome - 7 days;
- (53) salmonellosis - 24 hours;
- (54) severe acute respiratory syndrome (SARS) – 24 hours;
- (55) shigellosis - 24 hours;
- (56) smallpox - immediately;
- (57) Staphylococcus aureus with reduced susceptibility to vancomycin – 24 hours;
- (58) streptococcal infection, Group A, invasive disease - 7 days;
- (59) syphilis - 24 hours;
- (60) tetanus - 7 days;
- (61) toxic shock syndrome - 7 days;
- (62) trichinosis - 7 days;
- (63) tuberculosis - 24 hours;
- (64) tularemia – immediately;
- (65) typhoid - 24 hours;
- (66) typhoid carriage (Salmonella typhi) - 7 days;
- (67) typhus, epidemic (louse-borne) - 7 days;
- (68) vaccinia – 24 hours;
- (69) vibrio infection (other than cholera) – 24 hours;
- (70) whooping cough – 24 hours; and
- (71) yellow fever - 7 days.

(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 cayetanensis*, 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) Monkeypox.
 - (X) *Mycobacterium leprae*, the cause of leprosy.
 - (Y) *Plasmodium falciparum*, *P. malariae*, *P. ovale*, and *P. vivax*, the causes of malaria in humans.
 - (Z) Poliovirus (any), the cause of poliomyelitis.
 - (AA) Rabies virus.
 - (BB) *Rickettsia rickettsii*, the cause of Rocky Mountain spotted fever.
 - (CC) Rubella virus.
 - (DD) *Salmonella* spp., the causes of salmonellosis.
 - (EE) *Shigella* spp., the causes of shigellosis.
 - (FF) Smallpox virus, the cause of smallpox.
 - (GG) *Staphylococcus aureus* with reduced susceptibility to vanomycin.
 - (HH) *Trichinella spiralis*, the cause of trichinosis.

- (II) Vaccinia virus.
 - (JJ) Vibrio spp., the causes of cholera and other vibrioses.
 - (KK) Yellow fever virus.
 - (LL) 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;