Fiscal Note for addition to rule for North Carolina Division of Public Health
Requires OSBM Review

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 (See proposed rule text in Appendix)
Purpose of Addition:	Require laboratories that utilize electronic laboratory reporting (ELR) to report directly to the NC Division of Public Health all positive laboratory test results used to diagnosis hepatitis C infection (including hepatitis C antibody tests; nucleic acid tests for hepatitis C; hepatitis C antigen(s) tests, and hepatitis C genotypic tests). This augments the current requirement that only the acute form of hepatitis C is reportable by law in NC. The proposed amendment will provide NC public health authorities with the data needed to estimate the burden of chronic hepatitis C in NC and more precisely direct public health activities and scarce resources that address chronic hepatitis C.
Relevant Statutes:	GS 130A-134; 130A-139; 130A-141
State Agency Impact:	Yes
Local Agency Impact:	No
Private-Sector Impact	No
Substantial Economic Impact:	No

Background

North Carolina Communicable Disease Branch

The core mission of the Communicable Disease Branch (CDB) of the North Carolina (NC) Division of Public Health Epidemiology Section is to identify, prevent, and control communicable diseases to protect the public's health. As part of this mission, the Branch conducts surveillance for communicable diseases, including HIV, other sexually transmitted diseases (STDs), and other diseases reportable under NC law. Branch staff review case report data and provide consultation and assistance to local health departments (LHDs) and others to investigate disease cases and outbreaks, determine appropriate control measures to mitigate disease transmission, and ensure that control measures are applied. Disease surveillance data are used to identify affected populations and potential public health interventions, allocate resources, and evaluate public health programs.

Electronic Laboratory Reporting

Electronic Laboratory Reporting (ELR) is the electronic transmission from laboratories to public health of laboratory reports which identify reportable conditions. ELR improves the timeliness, accuracy, and completeness of data reported for surveillance. As of January 2016, 24 out of 100 hospitals facility and commercial laboratories utilize ELR to transmit laboratory reports for reportable conditions to the NC Division of Public Health. Approximately 71% of all reportable disease data submitted to NC DHHS are received through ELR. All remaining hospital laboratories and commercial laboratories are in process of moving to electronic laboratory reporting.

Hepatitis C Virus Infection

Hepatitis C virus (HCV) is a blood-borne virus most commonly transmitted through injection drug use. Although HCV infection (i.e., hepatitis C) can be acute and self-limiting, approximately 75%–85% of infected individuals develop chronic disease. Chronic HCV infection is a serious disease than can result in long-term health problems (i.e., chronic

liver disease, cirrhosis, and liver cancer) or death. According to the Centers for Disease Control and Prevention (CDC), nearly 30% of HCV-infected persons will die of HCV-related complications. Although highly effective treatments are now available, most individuals with chronic HCV infection are unaware of their infection and thus do not receive recommended care and treatment. Serious negative health outcomes for HCV-infected persons can be avoided by improved HCV screening and linkage to care and treatment.

Through public health surveillance for HCV infection, including outbreak detection and the monitoring of trends over time, public health activities and scarce resources can be more precisely directed to address the challenge of HCV. For example, HCV surveillance data can inform targeted HCV screening and linkage to care and treatment activities in communities most affected by HCV. According to the CDC and as of 2013, the most recent year for which information is available, 41 states have mandatory acute HCV infection case reporting to public health and 32 states have mandatory chronic HCV infection case reporting to public health. Currently, acute, but not chronic, HCV infection case reporting is mandatory in NC.

By NC law, healthcare providers, but not laboratories, must report acute HCV infection to public health authorities. Following an initial notification, the LHD conducts an epidemiologic investigation to confirm that the infection meets the Counsel of State and Territorial Epidemiologists (CSTE) acute HCV infection surveillance case definition, which requires distinct symptomatic illness. Since 2010, the CDB has observed a three-fold increase in reported acute HCV infections, from 39 in 2010 to 143 in 2015. However, considering the variability of symptomatic illness, lack of a specific diagnostic test for acute HCV infection, and the possibility of underreporting, the number of acute HCV infections in NC is likely underestimated.

Current reporting requirements facilitate public health surveillance for acute HCV infection, including outbreak detection and the monitoring of trends over time. However, the burden of chronic HCV infection in NC cannot be determined under the current reporting requirements. Instead, national estimates of chronic HCV infection prevalence are used to calculate the burden of chronic HCV infection in NC. Based on the CDC's national prevalence projections and US census data, the CDB estimates that 110,000 people (range: 80,000–150,000 people) in NC are living with chronic HCV infection. Lack of surveillance for chronic HCV infection in NC limits the ability to provide accurate burden estimates to state leadership and precisely direct public health activities and scarce resources, including testing and linkage to care and treatment.

An amendment to the NC Reportable Diseases and Conditions rule is needed to require laboratories that perform HCV testing and utilize ELR reporting to report positive laboratory results directly to the NC Division of Public Health. At a minimal cost, this amendment will provide benefit to North Carolinians by providing public health authorities with the data needed to estimate the burden of chronic HCV infection in NC and more precisely direct public health activities and scarce resources that address chronic HCV infection, including HCV screening and linkage to care and treatment activities.

Impact

State Agency Impact

The proposed amendment will have a fiscal impact on the State Agency. The NC Division of Public Health Information Technology team will update the North Carolina Electronic Disease Surveillance System (NC EDSS) at one-time cost of $76,200. This update will include development and implementation of the case processor, allowing NC EDSS to receive positive HCV laboratory test results via ELR. The estimation of this one-time costs is based on the annual total compensation for IT technical analysts, salary plus 52% in benefits,[1] and the level of effort required from them to modify the NC EDSS system so that it accepts Hep-C test results and populates the NC disease management system with the results. This modification involves coding and testing (see Table 1 for a derivation of this cost).

[1] 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

Table 1. Assumptions in Estimation of Initial Cost to State from the Proposed Rule

Task	Complexity	Man Days	Hours	AVG Cost per Hour for needed resources	Total Cost
Workflow/Report Impact Analysis	Low	0.5	4	100	$400
Case processor/CDC Extract Specifications/Write Review Approve	Medium	5	40	100	$4,000
Establish **New Disease**	Low	0.25	2	100	$200
Update LOINC Reference Groups with subgroups	Low	0.25	2	100	$200
Update Model For New Disease: Assumption same as acute	Low	0.25	2	100	$200
Code Case Processor Changes	Medium	10	80	100	$8,000
Test Case Processor/ELR Import Changes	Medium	6	48	100	$4,800
Code NETSS Changes: Assumption no special Extension data	Low	2	16	100	$1,600
Test NETSS Changes	Medium	3	24	100	$2,400
New workflows - Estimate 3	Unknown	1	8	100	$800
Test New workflows	Medium	2	16	100	$1,600
Update Existing Workflows - estimate 20	Low	2	16	100	$1,600
New Reports - Estimate 2 (Include Spec, design and coding)	Medium	10	80	100	$8,000
Test New Reports	Medium	10	80	100	$8,000
Simple Genotype Import: Map to template display; change import mapping	Medium	5	40	100	$4,000
IMPLEMENT HEP C		2	16	100	$1,600
Import Historical HEP C Lab Tests	Low	1	8	100	$800
De-duplicate Historical HEP C Persons/Events	Low	5	40	50	$2,000
TOTAL SALARY COST					$50,200
TOTAL COST (SALARY + COMPENSATION)					$76,200

This rule amendment will also impose an annual maintenance cost to the State Agency of $11,446, which will include maintaining the ELR feed, importing the data NC EDSS, and analyzing and reporting on the data. Ongoing maintenance is for quality assurance activities to ensure the results received meet the required standards. Please see below for level of effort required for maintenance and the estimated staff cost (salary plus benefits) associated with each item:

1. Help Desk (5% of 1 FTE) - $2,877
2. Epidemiology (5% of 1 FTE) - $4,819
3. ELR maintenance (2.5% of FTE) - $3,750

It is important to note that both the initial and on-going costs to the state are opportunity costs of existing resources, and there is no additional budgetary expense to meet this requirement.

Local Agency Impact

The proposed amendment has no direct impact on LHDs. LHD responsibilities surrounding epidemiologic investigation and reporting of acute HCV infection remain unchanged by this amendment. All other HCV-positive laboratory data will be managed by the CDB. With this amendment, LHDs will continue to investigate reports of acute hepatitis C from providers and hospitals, just as before. There will be no change in how LHDs receive these acute hepatitis C case reports or investigate potential cases. All ELR data will be received by and maintained through the state. Authorized LHD users will have the ability to look at these data (from their jurisdiction), if they desire, but there will be no additional action for LHDs to take based on these data. For example, during the course of an acute HCV infection case investigation, an authorized LHD user may access the state repository of chronic HCV infection cases for their jurisdiction. If the reported case is already a known chronically HCV-infected person, the LHD could cease their investigation, saving LHD time and resources.

Private-Sector Impact

The proposed amendment will have little to no cost on the private sector. Laboratories are not mandated to initiate ELR with this amendment. However, upon initiating ELR to transmit reportable disease test results to public health, laboratories must meet this new reporting requirement. No unique actions are required for reporting positive HCV laboratory tests via ELR; these results would simply be included in the ELR transmissions already being send to public health for other reportable diseases. Therefore, the requirement to transmit all positive HCV test results poses little, if any, additional burden on laboratories. With this amendment, reporting requirements remain unchanged for physicians, other healthcare providers, and healthcare facilities, with the exception of healthcare facility laboratories that utilize ELR. For the same reasons as above, this new requirement would pose a minimal additional cost, if any, to laboratories that are currently not using ELR but plan to start electronic transmission to DPH of laboratory results in the future.

Public Impact

The proposed amendment will benefit the public by providing NC public health authorities with the data needed to estimate the burden of chronic hepatitis C across the state and more precisely direct public health activities and scarce resources that address chronic hepatitis C, including HCV screening and linkage to care and treatment activities. By giving public health authorities access to better information on the impact of hepatitis C, this proposal may in the future lead to a decrease incidence of hepatitis C in the North Carolinian population and potentially even prevent deaths that are related to this disease. Given all the unknowns and the fact that hepatitis C deaths are not separately reported (they may be reported as chronic liver disease, cirrhosis, and liver cancer), it is difficult to estimate any potential public health benefits that would result from this reporting requirement. However, the agency is confident that future health benefits that would result from better targeted actions as a result of access to better information would outweigh the costs to DPH presented in Table 2 below.

Table 2. Resources and costs associated with the reporting of all positive laboratory test results used to diagnosis hepatitis C virus infection in North Carolina

Resources	Cost
A. Impact on State Agency	
Upgrades to NC EDSS* to receive HCV case reports	$76,200 (one-time cost)
Maintenance cost	$11,446 per year (annual cost)
Total one-time cost to State Agency	$76,200
Total annual cost to State Agency	$ 11,446
B. Impact on Local Agencies	
None	$0
C. Impact on Private Sector	
None	$0
Total cost	
Total one-time cost	$76,200
Total annual cost	$ 11,446

*North Carolina Electronic Disease Surveillance System

Costs include total compensation for state staff (NC 2015 Compensation and Benefits Report)

APPENDIX
Proposed Rule Text

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.

(d) Laboratories utilizing electronic laboratory reporting (ELR) shall report:
(1) All positive laboratory results from tests used to diagnosis hepatitis C infection, including:
(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
(D) Hepatitis C genotypic tests

History Note: *Authority G.S. 130A-134; 130A-135; 130A-139; 130A-141;*
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