

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 Citation: 10A NCAC 41A .0101 (Reportable Diseases and Conditions)

Purpose of Addition:

Establish rules necessary to implement surveillance and reporting of

1. Carbapenem-resistant Enterobacteriaceae (CRE)

Require:

- I. Laboratories with the capacity to detect carbapenemase producing CRE (CP-CRE) to report *Enterobacter* spp, *E.coli* or *Klebsiella* spp positive for a known carbapenemase resistance mechanism or positive on a phenotypic test for carbapenemase production directly to the NC Division of Public Health
- II. Laboratories without the capacity to detect CP-CRE to report *Enterobacter* spp, *E.coli* or *Klebsiella* spp resistant to any carbapenem directly to the NC Division of Public Health*
- III. Clinicians to report to public health authorities a person whose healthcare record contains a diagnosis of CRE, CP-CRE, KPC, NDM, OXA-48, IMP or VIM or novel carbapenemase

*It is requested that laboratories submit these isolates to the State Laboratory of Public Health for additional characterization

2. *Candida auris* causing clinical infection and colonization in people.

Require:

- I. Laboratories to report: culture of *Candida auris* from any body site including blood, wound, skin, ear, urine, rectum, respiratory secretions, or other body fluids.
- II. Require clinicians to report healthcare record diagnosis of *C. auris*

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

State Agency Impact: Yes

Local Agency Impact: Yes

Private-Sector Impact: Yes

Substantial Economic Impact: No

Significant Rule Change: Yes

Reason for Proposed Amendment: This rule amendment proposes to add two healthcare associated infections (HAIs) to the required list of reportable diseases and conditions. These HAIs are CP-CRE and *C. auris*.

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 healthcare associated infections (HAIs) 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.

Surveillance for Healthcare Associated and Resistant Pathogens Patient Safety (SHARPPS) Program

Preventing and responding to HAIs and antimicrobial resistant pathogens is a critical and growing public health need. The U.S. Centers for Disease Control and Prevention (CDC) estimates that 5% of all hospital admissions result in a healthcare associated infection, culminating in approximately 1.7 million infections and 99,000 deaths each year. Antibiotic resistant bacteria lead to at least 2 million infections and at least 23,000 deaths each year. The mission of the SHARPPS program is to work in partnerships to prevent, detect, and respond to events and outbreaks of healthcare-associated and antimicrobial resistant infections in North Carolina.

Surveillance of HAIs can provide SHARPPS with insight into the specific prevalence of infections in North Carolina and provide the data needed to develop prevention and treatment strategies across the state. An analysis of HAI data can facilitate a coordinated response involving public health, healthcare providers and the public is needed to address this threat to the health and safety of North Carolina Residents.

Reporting of healthcare-associated infection data will have little or no direct impact or opportunity cost for facilities submitting data. There are, however, potential significant second-order (i.e. indirect) impacts on hospitals and the general public associated with public disclosure of HAI data. However, any potential second-order benefits of HAI surveillance and reporting can only be realized if the data are appropriately validated and analyzed, including risk-adjustment based on characteristics of the facility and patient population. In general, any health benefits, cost savings, and costs associated with public disclosure of healthcare-associated infections are highly uncertain based on currently available research. Since research has not yet validated the potential impacts of HAI disclosure, these potential impacts are not included in this fiscal note.

Multi-drug resistant organisms (MDROs)

MDROs are organisms that have developed resistance to multiple types of antimicrobials. Antibiotic resistance limits our ability to use existing antibiotics to treat infections, increases the cost of health care, and results in greater disability and death. MDROs can cause infections in almost any part of the body, including the blood, lungs, urinary tract, wounds or skin. Symptoms vary based on the site that is infected (e.g., cough if in the lungs, urinary symptoms if in the bladder). The severity of these infections depends on the type of organism that causes the infection and the site of the body where the infection occurs. Thus, severity of illness can vary from small skin infections that are easily and quickly treated with appropriate wound care to life threatening infections of the blood, lungs, or nervous system that can take months to treat.

Enterobacteriaceae are a large group of bacteria that are a normal part of the human gut flora. Common examples are *Klebsiella* species and *Escherichia coli* (E. coli). Carbapenem-resistant Enterobacteriaceae (CRE) are Enterobacteriaceae that have become resistant to carbapenem antibiotics. Carbapenem antibiotics are often used as the last line of treatment for infections caused by highly resistant bacteria, including those in the Enterobacteriaceae family. Some CRE produce carbapenemases - enzymes that break down carbapenem antibiotics. Examples of carbapenemases include *Klebsiella pneumoniae*

carbapenemase [KPC], New Delhi metallo- β -lactamase [NDM], Verona integron-encoded metallo- β -lactamase [VIM], imipenemase [IMP] metallo- β -lactamase, and OXA-48 carbapenemase. The genes that produce these carbapenemases can be transferred to other bacteria. Because of this ability to transfer resistance to other bacteria, carbapenemase-producing CRE (CP-CRE) are of particular concern. Infections caused by CRE can be hard-to-treat or untreatable and are on the rise. CDC classifies CRE as an urgent public health threat.

In September 2016, the NC Communicable Disease Branch (CDB) in partnership with the NC State Laboratory of Public Health (SLPH) and seven major healthcare facilities completed an 18 month CRE sentinel surveillance project. A subsequent evaluation of this surveillance system concluded that the surveillance system was useful in describing the burden of CRE in NC as well as in detection of clusters of CRE within facilities.

Candida auris is an emerging fungus that presents a serious global health threat. Most strains of *C. auris* are resistant to at least one antifungal drug. Nearly half (41%) are resistant to two drug classes and some are resistant to all three drug classes approved for treatment of fungal infections. Unlike other *Candida* species, *C. auris* can spread from patient to patient within healthcare facilities and contaminate healthcare environments, much like methicillin-resistant *Staphylococcus aureus* and multidrug-resistant *Acinetobacter*.

Known risk factors for *C. auris* infection are similar to those for invasive *Candida* infection in general, including central venous catheter use, recent surgery, diabetes, and recent broad-spectrum antibiotic or antifungal use. In the United States, *C. auris* has been observed predominantly among patients with extensive exposure to nursing homes and short-term and long-term acute care hospitals. *C. auris* is known to cause bloodstream infections, wound infections, and ear infections. It can also colonize the urinary tract and the respiratory tract without causing symptoms. In some hospitals abroad, *C. auris* has emerged as the leading cause of candida bloodstream infections, accounting for up to 40% of *Candida* isolates.

C. auris requires specialized laboratory methods for identification and can be misidentified as other yeast (especially *Candida haemulonii*) by some testing methods. Misidentification may lead to inappropriate treatment of *C. auris*, making it difficult to control its spread in healthcare settings.

Early detection and aggressive implementation of infection prevention and control strategies are necessary to prevent further spread of both *C. auris* and CRE. These strategies require an understanding of the prevalence or incidence of these conditions. Public health authorities must be notified promptly when cases of CRE or *C. auris* are detected in order to contain these MDROs. Required reporting and subsequent analysis will provide data to develop and implement the prevention and control measures to reduce the burden imposed by HAIs.

In June of 2017, the Council of State and Territorial Epidemiologists (CSTE) passed a position statement which adds CP-CRE to the nationally notifiable condition list and recommends that all states and territories enact laws to make CP-CRE reportable in their jurisdiction. CSTE also passed a position statement providing a standardized case definition to allow for public health tracking of *C. auris* cases, which will be helpful in containing its spread within and between healthcare facilities and networks.

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 2018, 33 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.

Opportunity Cost

Reporting of CRE in North Carolina

Figure 1 shows the total estimated impact of this rule change. The estimates for time spent on the investigation (both public and private sector) comes from time spent on recent case investigations of CRE in North Carolina.

The impact on the county agencies was estimated based on mean hourly wage of \$19.59 for a Public Health Nurse II, 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.¹ The impact on the state agency was estimated based on the mean hourly wage for a State Public Health Epidemiologist I of \$59 and for a State 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.² The cost for the time of the private sector Medical Laboratory Technician and Registered Nurse is based on their wage of \$20.05 and 34.70 respectively, which was obtained from the 2016 State Occupational Employment and Wage Estimates in NC published by the Bureau of Labor Statistics³ and an assumption of benefits of 42%.⁴

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

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 \$19,597. The estimation is based on the annual total compensation for IT technical analysts, salary plus 52% in benefits, and time required to develop and implement the case processor to accept CRE and *C. auris* test results and develop relevant question packages within the NC EDSS system.

States with similar population size to NC report receiving 5-10 CRE reports each week. During NC DPH sentinel surveillance, an average of 5 CRE cases were reported from seven major healthcare systems each week. DPH staff would spend an estimated 2 hours on each reported CRE case.

The estimates included for *C. auris* in the figure are based on the total of 2 cases per year of vancomycin non-susceptible *Staphylococcus aureus* between 2012 and 2016 in North Carolina. To date, North Carolina has not reported a case of *C. auris*. Vancomycin non-susceptible *Staphylococcus aureus* is used as a proxy since it is

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

² NC Office of State Human Resources. Total Compensation Calculator. <http://oshr.nc.gov/state-employee-resources/classification-compensation/total-compensation-calculator>

³ Bureau of Labor Statistics. May 2016 State Occupational Employment and Wage Estimates North Carolina. http://www.bls.gov/oes/current/oes_nc.htm

⁴ 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>

another infrequently reported MDRO with significant public health implications that has been reportable in North Carolina since 1/1/2005. As of November 30, 2017, 203 clinical cases of *C. auris* had been reported in 10 states across the country.

The SHARPPS program is already conducting surveillance for these MDROs through voluntary reporting from physicians and laboratories. Surveillance data for both conditions would continue to be managed by the SHARPPS program. The SHARPPS program would use these data to provide information on the temporal, geographic, and demographic occurrence of these MDROs to facilitate prevention and control. Surveillance will also help to better understand the organism, transmission dynamics, pathogenicity, response to treatment, and resistance patterns. The aim is containment of CP-CRE and *C. auris*.

State laboratory personnel will facilitate shipping of isolates and will be conducting additional characterization of available CRE isolates. The state laboratory currently provides testing on isolates as needed, and will continue to expand their CRE testing services with or without this rule change. It is estimated that laboratory personnel would spend up to 1 hour per isolate. The Antimicrobial Resistant Laboratory Network and CDC are available to conduct further characterization of confirmed and suspected *C. auris* isolates at no additional cost to the state or the submitter.

Local Agency Impact

Local health department staff, in collaboration with the SHARPPS program would spend an increased amount of time on outbreak investigation and response efforts.

Private-Sector Impact

The proposed amendment will have minimal fiscal impact on the private sector. We are not requiring a change in testing practices, and there is minimal impact on healthcare providers and laboratories to report to communicable disease staff.

According to the 2017 CRE laboratory capacity survey disseminated by NC DPH, CRE were identified an average of seven times per facility per year in 2016. The daily burden of identifying and reporting this number of CRE cases will not be substantial.

NC laboratory task force consensus guidelines and other resources will be made available to the private sector. This will assist with addressing adopting current Clinical & Laboratory Standards Institute (CLSI) minimum inhibitory concentration (MIC) breakpoints for carbapenem antibiotics, and provide instruction for facilities who have not yet adopted the latest CLSI MIC breakpoints for carbapenems. This tool will also help increase awareness about the current CRE case definition. According to the 2017 CRE laboratory capacity survey, most microbiology laboratories in NC are not able to identify carbapenemase production. These laboratories will be asked to send CRE isolates to the SLPH for additional characterization. Minimal laboratory time would be required to prepare and ship isolates. Funding for shipment and testing is available through CDC's ARLN at no additional cost to the submitting laboratory.

Despite the variability in laboratory methods used to identify CRE, only 5 of 61 (8%) surveyed laboratories in NC mentioned any potential barriers to reporting CRE. These barriers included not performing microbiology in-house (in which case the laboratory performing CRE testing would report) and technical concerns. It is not mandated that laboratories initiate ELR.

Cost estimates for private sector impact consider time spent providing information to local health departments and time spent packaging and submitting isolates for additional testing.

All impacts are minimal opportunity costs involving existing state, local, and private sector staff. No additional expenditures are required. Please note that while this note reflects the cost of reporting, it does not focus on quantifying the benefits resulting from public health control measures associated with these conditions.

Figure 1

NC DPH Permanent Reporting of CRE & C. Auris				
Impact Analysis				
Projected Annual Cost				
A. Annual Impact on Private Sector				
Organism	# Estimated Events Reported	Total Hours per Event Reported	Hourly Salary of Private Sector Registered Nurse	Cost to Private Sector
CRE	390*	.5	\$49	\$9,555
<i>C.auris</i>	2	1.5	\$49	\$147
Organism	# Estimated Events Reported	Total Hours per Event Reported	Hourly Salary of Private Sector Medical Laboratory Technician	Cost to Private Sector
CRE	390*	.5	\$28	\$5,460
<i>C.auris</i>	2	.5	\$28	\$28
				Total Cost to Private Sector
				\$15,190
B. Annual Impact on State Agency: Division of Public Health, Epidemiology Section, Communicable Disease Branch				
Organism	# Estimated Events Reported	Total Hours per Event Reported	Hourly Salary of State Public Health Epidemiologist I	Cost to State Agency
CRE	390	2	\$84	\$65,520
<i>C. auris</i>	2	3	\$84	\$504
Organism	# Estimated Events Reported	Total Hours per Event Reported	Hourly Salary of Medical Laboratory Technician	Cost to State Agency
CRE	390	1	\$40	\$15,600
<i>C. auris</i>	2	1	\$40	\$80
Surveillance System Updates		Total Hours spent	Hourly Salary of IT analyst	One time Cost to State Agency
Upgrades to NC EDSS [^] to receive case reports				19,597
			Total Cost to State	
			One-time Costs	\$19,597
			Annual Costs	\$81,704
			Total Costs	\$168,301

C. Annual Impact on County Agencies: Local Health Department Communicable Disease Branch

Organism	# Events Reported	Total Hours per Event Reported	Hourly Total Compensation of Public Health Nurse II	Cost to County Agencies
CRE	390	1	\$30	\$11,700
<i>C. auris</i>	2	2	\$30	\$60
				Total Cost to County Agencies
				\$11,760
Total Annual Estimated Economic Impact				
Private Costs Sector		\$ 15,190		
State Gov't Costs		\$81,704		
Local Gov't		\$11,760		
Total Costs		\$108,654		

*not all 390 cases represent new burden of events; NC has received a median 136 reported CRE cases per year since 2015
 ^ North Carolina Electronic Disease Surveillance System

Appendix A:

CHAPTER 41 - EPIDEMIOLOGY HEALTH

SUBCHAPTER 41A - COMMUNICABLE DISEASE CONTROL

SECTION .0100 - COMMUNICABLE DISEASE CONTROL

10A NCAC 41A 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) Candida auris - 24 hours;
- ~~(6)~~(7) Carbapenem-Resistant Enterobacteriaceae – 24 hours (CRE);
- ~~(6)~~(8) chancroid - 24 hours;
- ~~(7)~~(9) chikungunya virus infection - 24 hours;
- ~~(8)~~(10) chlamydial infection (laboratory confirmed) - 7 days;
- ~~(9)~~(11) cholera - 24 hours;
- ~~(10)~~(12) Creutzfeldt-Jakob disease – 7 days;
- ~~(11)~~(13) cryptosporidiosis – 24 hours;
- ~~(12)~~(14) cyclosporiasis – 24 hours;
- ~~(13)~~(15) dengue - 7 days;
- ~~(14)~~(16) diphtheria - 24 hours;
- ~~(15)~~(17) Escherichia coli, shiga toxin-producing - 24 hours;
- ~~(16)~~(18) ehrlichiosis – 7 days;
- ~~(17)~~(19) encephalitis, arboviral - 7 days;
- ~~(18)~~(20) foodborne disease, including Clostridium perfringens, staphylococcal, Bacillus cereus, and other and unknown causes
- 24 hours;
- ~~(19)~~(21) gonorrhea - 24 hours;
- ~~(20)~~(22) granuloma inguinale - 24 hours;

~~(21)~~(23) Haemophilus influenzae, invasive disease - 24 hours;
~~(22)~~(24) Hantavirus infection – 7 days;
~~(23)~~(25) Hemolytic-uremic syndrome – 24 hours;
~~(24)~~(26) Hemorrhagic fever virus infection – immediately;
~~(25)~~(27) hepatitis A - 24 hours;
~~(26)~~(28) hepatitis B - 24 hours;
~~(27)~~(29) hepatitis B carriage - 7 days;
~~(28)~~(30) hepatitis C, acute – 7 days;
~~(29)~~(31) human immunodeficiency virus (HIV) infection confirmed - 24 hours;
~~(30)~~(32) influenza virus infection causing death – 24 hours;
~~(31)~~(33) legionellosis - 7 days;
~~(32)~~(34) leprosy – 7 days;
~~(33)~~(35) leptospirosis - 7 days;
~~(34)~~(36) listeriosis – 24 hours;
~~(35)~~(37) Lyme disease - 7 days;
~~(36)~~(38) Lymphogranuloma venereum - 7 days;
~~(37)~~(39) malaria - 7 days;
~~(38)~~(40) measles (rubeola) - 24 hours;
~~(39)~~(41) meningitis, pneumococcal - 7 days;
~~(40)~~(42) meningococcal disease - 24 hours;
~~(41)~~(43) Middle East respiratory syndrome (MERS) - 24 hours;
~~(42)~~(44) monkeypox – 24 hours;
~~(43)~~(45) mumps - 7 days;
~~(44)~~(46) nongonococcal urethritis - 7 days;
~~(45)~~(47) novel influenza virus infection – immediately;
~~(46)~~(48) plague - immediately;
~~(47)~~(49) paralytic poliomyelitis - 24 hours;
~~(48)~~(50) pelvic inflammatory disease – 7 days;
~~(49)~~(51) psittacosis - 7 days;
~~(50)~~(52) Q fever - 7 days;
~~(51)~~(53) rabies, human - 24 hours;

(52)(54) Rocky Mountain spotted fever - 7 days;

(53)(55) rubella - 24 hours;

(54)(56) rubella congenital syndrome - 7 days;

(55)(57) salmonellosis - 24 hours;

(56)(58) severe acute respiratory syndrome (SARS) – 24 hours;

(57)(59) shigellosis - 24 hours;

(58)(60) smallpox - immediately;

(59)(61) Staphylococcus aureus with reduced susceptibility to vancomycin – 24 hours;

(60)(62) streptococcal infection, Group A, invasive disease - 7 days;

(61)(63) syphilis - 24 hours;

(62)(64) tetanus - 7 days;

(63)(65) toxic shock syndrome - 7 days;

(64)(66) trichinosis - 7 days;

(65)(67) tuberculosis - 24 hours;

(66)(68) tularemia – immediately;

(67)(69) typhoid - 24 hours;

(68)(70) typhoid carriage (Salmonella typhi) - 7 days;

(69)(71) typhus, epidemic (louse-borne) - 7 days;

(70)(72) vaccinia – 24 hours;

(71)(73) vibrio infection (other than cholera) – 24 hours;

(72)(74) whooping cough – 24 hours; and

(73)(75) 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~~ report electronically using laboratory reporting (ELR), secure telecommunication, or paper reports:

(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) Candida auris.
- (I) Carbapenem-Resistant Enterobacteriaceae (CRE).
- ~~(H)~~(J) Chlamydia trachomatis, the cause of genital chlamydial infection, conjunctivitis (adult and newborn) and pneumonia of newborns.
- ~~(H)~~(K) Clostridium botulinum, a cause of botulism.
- ~~(H)~~(L) Clostridium tetani, the cause of tetanus.
- ~~(K)~~(M) Corynebacterium diphtheriae, the cause of diphtheria.
- ~~(L)~~(N) Coxiella burnetii, the cause of Q fever.
- ~~(M)~~(O) Cryptosporidium parvum, the cause of human cryptosporidiosis.
- ~~(N)~~(P) Cyclospora cayetanensis, the cause of cyclosporiasis.
- ~~(O)~~(Q) Ehrlichia spp., the causes of ehrlichiosis.
- ~~(P)~~(R) Shiga toxin-producing Escherichia coli, a cause of hemorrhagic colitis, hemolytic uremic syndrome, and thrombotic thrombocytopenic purpura.
- ~~(Q)~~(S) Francisella tularensis, the cause of tularemia.
- ~~(R)~~(T) Hepatitis B virus or any component thereof, such as hepatitis B surface antigen.
- ~~(S)~~(U) Human Immunodeficiency Virus, the cause of AIDS.
- ~~(T)~~(V) Legionella spp., the causes of legionellosis.
- ~~(U)~~(W) Leptospira spp., the causes of leptospirosis.
- ~~(V)~~(X) Listeria monocytogenes, the cause of listeriosis.
- ~~(W)~~(Y) Middle East respiratory syndrome virus.
- ~~(X)~~(Z) Monkeypox.
- ~~(Y)~~(AA) Mycobacterium leprae, the cause of leprosy.
- ~~(Z)~~(BB) Plasmodium falciparum, P. malariae, P. ovale, and P. vivax, the causes of malaria in humans.
- ~~(AA)~~(CC) Poliovirus (any), the cause of poliomyelitis.
- ~~(BB)~~(DD) Rabies virus.
- ~~(CC)~~(EE) Rickettsia rickettsii, the cause of Rocky Mountain spotted fever.
- ~~(DD)~~(FF) Rubella virus.
- ~~(EE)~~(GG) Salmonella spp., the causes of salmonellosis.
- ~~(FF)~~(HH) Shigella spp., the causes of shigellosis.
- ~~(GG)~~(II) Smallpox virus, the cause of smallpox.
- ~~(HH)~~(JJ) Staphylococcus aureus with reduced susceptibility to vanomycin.
- ~~(II)~~(KK) Trichinella spiralis, the cause of trichinosis.
- ~~(JJ)~~(LL) Vaccinia virus.
- ~~(KK)~~(MM) Vibrio spp., the causes of cholera and other vibrioses.
- ~~(LL)~~(NN) Yellow fever virus.

~~(MM)~~(OO) 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.
 - (5) Laboratory results from tests used to identify CRE, including when available, antimicrobial susceptibility testing, phenotypic and molecular tests.
- (d) Laboratories utilizing electronic laboratory reporting (ELR) shall ~~report~~ report in addition to those listed under (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; ~~and~~ or
 - (B) The pol region sequence (including all regions: protease (PR)/reverse transcriptase (RT) and integrase (INI) genes, if available).

(e) For the purposes of reporting Carbapenem-Resistant Enterobacteriaceae (CRE), the following results are reportable to the Division of Public Health:

- (1) detection of carbapenemase producing CRE (CP-CRE) through reports of *Enterobacter* spp, *E.coli* or *Klebsiella* spp positive for a known carbapenemase resistance mechanism or positive on a phenotypic test for carbapenemase production;
- (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;
- (3) Clinicians shall report a person whose healthcare record contains a diagnosis of CP-CRE, KPC, NDM, OXA-48, IMP or VIM or novel carbapenemase.

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.