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) – 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) cryptosporidiosis – 24 hours;
(18) cyclosporiasis – 24 hours;
(19) dengue - 7 days;
(20) diphtheria - 24 hours;
(21) Escherichia coli, shiga toxin-producing infection - 24 hours;
(22) ehrlichiosis – 7 days;
(23) foodborne disease, including Clostridium perfringens, staphylococcal, Bacillus cereus, and other and unknown causes - 24 hours;
(24) gonorrhea - 24 hours;
(25) granuloma inguinale - 24 hours;
(26) Haemophilus influenzae, invasive disease - 24 hours;
(27) Hantavirus infection – 7 days;
(28) Hemolytic-uremic syndrome – 24 hours;
(29) Hemorrhagic fever virus infection – immediately;
(30) hepatitis A - 24 hours;
(31) hepatitis B - 24 hours;
(32) hepatitis B carriage - 7 days;
(33) hepatitis C, acute – 7 days;
(34) human immunodeficiency virus (HIV) infection confirmed - 24 hours;
(35) influenza virus infection causing death – 24 hours;
(36) legionellosis - 7 days;
(37) leprosy – 7 days;
(38) leptospirosis - 7 days;
(39) listeriosis – 24 hours;
(40) Lyme disease - 7 days;
(41) Lymphogranuloma venereum - 7 days;
(42) malaria - 7 days;
(43) measles (rubeola) - immediately;

(44) meningitis, pneumococcal – 7 days;
(45) meningococcal disease – 24 hours;
(46) Middle East respiratory syndrome (MERS) – 24 hours;
(47) monkeypox – 24 hours;
(48) mumps – 7 days;
(49) nongonococcal urethritis – 7 days;
(50) novel coronavirus infection causing death – 24 hours;
(51) novel coronavirus infection – immediately;
(52) novel influenza virus infection – immediately;
(53) plague – immediately;
(54) paralytic poliomyelitis – 24 hours;
(55) pelvic inflammatory disease – 7 days;
(56) psittacosis – 7 days;
(57) Q fever – 7 days;
(58) rabies, human – 24 hours;
(59) rubella – 24 hours;
(60) rubella congenital syndrome – 7 days;
(61) salmonellosis – 24 hours;
(62) severe acute respiratory syndrome (SARS) – 24 hours;
(63) shigellosis – 24 hours;
(64) smallpox – immediately;
(65) spotted fever rickettsiosis – 7 days;
(66) Staphylococcus aureus with reduced susceptibility to vancomycin – 24 hours;
(67) streptococcal infection, Group A, invasive disease – 7 days;
(68) syphilis – 24 hours;
(69) tetanus – 7 days;
(70) toxic shock syndrome – 7 days;
(71) trichinosis – 7 days;
(72) tuberculosis – 24 hours;
(73) tularemia – immediately;
(74) typhoid – 24 hours;
(75) typhoid carriage (Salmonella typhi) – 7 days;
(76) typhus, epidemic (louse-borne) – 7 days;
(77) vaccinia – 24 hours;
(78) varicella – 24 hours;
(79) vibrio infection (other than cholera) – 24 hours;
(80) whooping cough – 24 hours;
(81) yellow fever – 7 days; and
(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 or hemorrhagic fever virus.

(C) Arthropod-borne virus (any type).
(D) Babesia spp., the cause of babesiosis.
(E) Bacillus anthracis, the cause of anthrax.
(F) Bordetella pertussis, the cause of whooping cough (pertussis).
(G) Borrelia burgdorferi, the cause of Lyme disease (confirmed tests).
(H) Brucella spp., the causes of brucellosis.
(I) Campylobacter spp., the causes of campylobacteriosis.
(J) Candida auris.
(K) Carbapenem-Resistant Enterobacteriaceae (CRE).
(L) Chlamydia trachomatis, the cause of genital chlamydial infection, conjunctivitis (adult and newborn) and pneumonia of newborns.
(M) Clostridium botulinum, a cause of botulism.
(N) Clostridium tetani, the cause of tetanus.
(O) Coronavirus, novel human strain.
(P) Corynebacterium diphtheriae, the cause of diphtheria.
(Q) Coxiella burnetii, the cause of Q fever.
(R) Cryptosporidium spp., the cause of human cryptosporidiosis.
(S) Cyclospora cayetanesis, the cause of cyclosporiasis.
(T) Dengue virus.
(U) Ehrlichia spp., the causes of ehrlichiosis.
(V) Shiga toxin-producing Escherichia coli, a cause of hemorrhagic colitis, hemolytic uremic syndrome, and thrombotic thrombocytopenic purpura.
(W) Francisella tularensis, the cause of tularemia.
(X) Hepatitis A virus.
(Y) Hepatitis B virus or any component thereof, such as hepatitis B surface antigen.
(Z) Human Immunodeficiency Virus, the cause of AIDS.
(AA) Legionella spp., the causes of legionellosis.
(BB) Leptospira spp., the causes of leptospirosis.
(CC) Listeria monocytogenes, the cause of listeriosis.
(DD) Measles virus.
(EE) Middle East respiratory syndrome virus.
(FF) Monkeypox.
(GG) Mumps virus.
(HH) Mycobacterium leprae, the cause of leprosy.
(II) Plasmodium falciparum, P. malariae, P. ovale, and P. vivax, the causes of malaria in humans.
(JJ) Poliovirus (any), the cause of poliomyelitis.
(KK) Rabies virus.
(LL) Rickettsia spp., the cause of spotted fever rickettsiosis.
(MM) Rubella virus.
(NN) Salmonella spp., the causes of salmonellosis.
(OO) Shigella spp., the causes of shigellosis.
(PP) Smallpox virus, the cause of smallpox.
(QQ) Staphylococcus aureus with reduced susceptibility to vanomycin.
(RR) Trichinella spiralis, the cause of trichinosis.
(SS) Vaccinia virus.
(TT) Varicella virus.
(UU) Vibrio spp., the causes of cholera and other vibrioses.
(VV) Yellow fever virus.
(WW) Yersinia pestis, the cause of plague.
(XX) Zika virus.

(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 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 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.

(e) 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. July 1, 2020.

10A NCAC 41A .0102 METHOD OF REPORTING

(a) When a report of a disease or condition is required to be made pursuant to G.S. 130A-135 through 139 and 10A NCAC 41A .0101, with the exception of laboratories, which shall proceed as in Subparagraph (d), the report shall be made to the local health director as follows:

(1) For diseases and conditions required to be reported within 24 hours, the initial report shall be made by telephone, and the report required by Subparagraph (2) of this Paragraph shall be made within seven days.

(2) In addition to the requirements of Subparagraph (1) of this Paragraph, the report shall be made on the communicable disease report card or in an electronic format provided by the Division of Public Health and shall include the name and address of the patient, the name and address of the parent or guardian if the patient is a minor, and epidemiologic information.

(3) In addition to the requirements of Subparagraphs (1) and (2) of this Paragraph, forms or electronic formats provided by the Division of Public Health for collection of information necessary for disease control and documentation of clinical and epidemiologic information about the cases shall be completed and submitted for the following reportable diseases and conditions identified in 10A NCAC 41A .0101(a):

(A) acquired immune deficiency syndrome (AIDS);
(B) brucellosis;
(C) cholera;
(D) cryptosporidiosis;
(E) cyclosporiasis;
(F) E. coli 0157:H7 infection;
(G) ehrlichiosis;
(H) Haemophilus influenzae, invasive disease;
(I) Hemolytic-uremic syndrome/thrombotic thrombocytopenic purpura;
(J) hepatitis A;
(K) hepatitis B;
(L) hepatitis B carriage;
(M) hepatitis C;
(N) human immunodeficiency virus (HIV) confirmed;
(O) legionellosis;
(P) leptospirosis;
(Q) Lyme disease;
(R) malaria;
(S) measles (rubeola);
(T) meningitis, pneumococcal;

(U) meningococcal disease;
(V) mumps;
(W) paralytic poliomyelitis;
(X) psittacosis;
(Y) Rocky Mountain spotted fever;
(Z) rubella;
(AA) rubella congenital syndrome;
(BB) tetanus;
(CC) toxic shock syndrome;
(DD) trichinosis;
(EE) tuberculosis;
(FF) tularemia;
(GG) typhoid;
(HH) typhoid carriage (Salmonella typhi);
(II) vibrio infection (other than cholera); and
(JJ) whooping cough.

Communicable disease report cards, surveillance forms, and electronic formats are available from the Division of Public Health, 1915 Mail Service Center, Raleigh, North Carolina 27699-1915, and from local health departments.

(b) Notwithstanding the time frames established in 10A NCAC 41A .0101, a restaurant or other food or drink establishment shall report all outbreaks or suspected outbreaks of foodborne illness in its customers or employees and all suspected cases of foodborne disease or foodborne condition in food-handlers at the establishment by telephone to the local health department within 24 hours in accordance with Subparagraph (a)(1) of this Rule. However, the establishment is not required to submit a report card or surveillance form pursuant to Subparagraph (a)(2) of this Rule.

(c) For the purposes of reporting by restaurants and other food or drink establishments pursuant to G.S.130A-138, the following diseases and conditions listed in 10A NCAC 41A .0101(a) shall be reported:

(1) anthrax;
(2) botulism;
(3) brucellosis;
(4) campylobacter infection;
(5) cholera;
(6) cryptosporidiosis;
(7) cyclosporiasis;
(8) E. coli 0157:H7 infection;
(9) hepatitis A;
(10) salmonellosis;
(11) shigellosis;
(12) streptococcal infection, Group A, invasive disease;
(13) trichinosis;
(14) tularemia;
(15) typhoid;
(16) typhoid carriage (Salmonella typhi); and
(17) vibrio infection (other than cholera).

(d) Laboratories required to report test results pursuant to G.S. 130A-139 and 10A NCAC 41A .0101(c) shall report as follows:

(1) The results of the specified tests for syphilis, chlamydia and gonorrhea shall be reported to the local health department by the first and fifteenth of each month. Reports of the results of the specified tests for gonorrhea, chlamydia and syphilis shall include the specimen collection date, the patient's age, race, and sex, and the submitting physician's name, address, and telephone numbers.
(2) Positive darkfield examinations for syphilis, all reactive prenatal and delivery STS titers, all reactive STS titers on infants less than one year old and STS titers of 1:8 and above shall be reported within 24 hours by telephone to the HIV/STD Prevention and Care Branch at (919) 733-7301, or the HIV/STD Prevention and Care Branch Regional Office where the laboratory is located.

(3) With the exception of positive laboratory tests for human immunodeficiency virus, positive laboratory tests as defined in G.S. 130A-139(1) and 10A NCAC 41A .0101(c) shall be reported to the Division of Public Health electronically, by mail, by secure telefax or by telephone within the time periods specified for each reportable disease or condition in 10A NCAC 41A .0101(a). Confirmed positive laboratory tests for human immunodeficiency virus as defined in 10A NCAC 41A .0101(b) and for CD4 results defined in 10A NCAC 41A .0101(c)(4) shall be reported to the HIV/STD Prevention and Care Branch within 24 hours of obtaining reportable test results. Reports shall include as much of the following information as the laboratory possesses:

(A) the specific name of the test performed;
(B) the source of the specimen;
(C) the collection date(s);
(D) the patient's name, age, race, sex, address, and county; and
(E) the submitting physician's name, address, and telephone number.

History Note: *Authority G.S. 130A-134; 130A-135; 130A-138; 130A-139; 130A-141;*
Temporary Rule Eff. February 1, 1988, for a period of 180 days to expire on July 29, 1988;
Eff. March 1, 1988;
Amended Eff. October 1, 1994; February 3, 1992; December 1, 1991; May 1, 1991;
Temporary Amendment Eff. December 16, 1994, for a period of 180 days or until the permanent rule becomes effective, whichever is sooner;
Temporary Amendment Expired June 16, 1995;
Amended Eff. December 1, 2007; November 1, 2007; August 1, 2005, April 1, 2003; August 1, 1998;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. January 9, 2018.

10A NCAC 41A .0103 DUTIES OF LOCAL HEALTH DIRECTOR: REPORT COMMUNICABLE DISEASES

(a) Upon receipt of a report of a communicable disease or condition pursuant to 10A NCAC 41A .0101, the local health director shall:

(1) immediately investigate the circumstances surrounding the occurrence of the disease or condition to determine the authenticity of the report and the identity of all persons for whom control measures are required. This investigation shall include the collection and submission for laboratory examination of specimens necessary to assist in the diagnosis and indicate the duration of control measures;
(2) determine what control measures have been given and ensure that proper control measures as provided in 10A NCAC 41A .0201 have been given and are being complied with;
(3) forward the report as follows:
(A) The local health director shall forward all authenticated reports made pursuant to G.S. 130A-135 to 137 of syphilis, chancroid, granuloma inguinale, and lymphogranuloma venereum within seven days to the regional office of the Division of Public Health. In addition, the local health director shall telephone reports of all cases of primary, secondary, and early latent (under one year's duration) syphilis to the regional office of the HIV/STD Prevention and Care Branch within 24 hours of diagnosis at the health department or report by a physician.
(B) The local health director shall telephone all laboratory reports of reactive syphilis serologies to the regional office of the Division of Public Health within 24 hours of receipt if the person tested is pregnant. This shall also be done for all other persons tested unless the dilution is less than 1:8 and the person is known to be over 25 years of age or has been previously treated. In addition, the written reports shall be sent to the regional office of the Division of Public Health within seven days.
(C) Except as provided in (a)(3)(A) and (B) of this Rule, a local health director who receives a report pursuant to 10A NCAC 41A .0102 regarding a person residing in that jurisdiction shall forward the authenticated report to the Division of Public Health within seven days.

(D) Except as provided in (a)(3)(A) and (B) of this Rule, a local health director who receives a report pursuant to 10A NCAC 41A .0102 regarding a person who resides in another jurisdiction in North Carolina shall forward the report to the local health director of that jurisdiction within 24 hours. A duplicate report card marked "copy" shall be forwarded to the Division of Epidemiology within seven days.

(E) A local health director who receives a report pursuant to 10A NCAC 41A .0102 regarding a person who resided outside of North Carolina at the time of onset of the illness shall forward the report to the Division of Public Health within 24 hours.

(b) If an outbreak exists, the local health director shall submit to the Division of Public Health within 30 days a written report of the investigation, its findings, and the actions taken to control the outbreak and prevent a recurrence.

(c) Whenever an outbreak of a disease or condition occurs which is not required to be reported by 10A NCAC 41A .0101 but which represents a significant threat to the public health, the local health director shall give appropriate control measures consistent with 10A NCAC 41A .0200, and inform the Division of Public Health of the circumstances of the outbreak within seven days.

History Note: *Authority G.S. 130A-141; 130A-144;*
Temporary Rule Eff. February 1, 1988, for a period of 180 days to expire on July 29, 1988;
Eff. March 1, 1988;
Amended Eff. April 1, 2003; December 1, 1991; September 1, 1990;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. January 9, 2018.

10A NCAC 41A .0104 RELEASE OF COMMUNICABLE DISEASE RECORDS: RESEARCH PURPOSES

(a) A person may request, for bona fide research purposes, the release of records which pertain to a communicable disease or communicable condition and which identify individuals. The request shall be in writing and shall contain the following information:

(1) Name of organization requesting the data;
(2) Names of principal investigators;
(3) Name of project;
(4) Purpose of project;
(5) Description of the proposed use of the data, including protocols for contacting patients, relatives, and service providers;
(6) Descriptions of measures to protect the security of the data;
(7) An assurance that the data will not be used for purposes other than those described in the protocol;
(8) An assurance that the data will be properly disposed of upon completion of the project; and
(9) An assurance that the results of the project will be provided to the custodian of the records.

(b) The request for release of the records shall be granted or denied in writing based upon the following considerations:

(1) Whether the objectives of the project require patient identifying information;
(2) Whether the objective of the project can be reached with the use of the data;
(3) Whether the project has a reasonable chance of answering a legitimate research question;
(4) Whether the project might jeopardize the ability of the Epidemiology Division to obtain reports and information regarding communicable diseases and communicable conditions;
(5) Whether the patient's right to privacy would be adequately protected.

History Note: *Authority G.S. 130A-143(9);*
Temporary Rule Eff. February 1, 1988, for a period of 180 days to expire on July 29, 1988;
Eff. March 1, 1988;
Amended Eff. September 1, 1991;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. January 9, 2018.

10A NCAC 41A .0105 HOSPITAL EMERGENCY DEPARTMENT DATA REPORTING

Hospitals, as defined in G.S. 130A-480(d), shall submit electronically to the Division of Public Health the following electronically available emergency department data elements for all emergency department visits:

(1) Patient record number or other unique identification number;
(2) Patient date of birth and age;
(3) Patient's sex;
(4) City of residence;
(5) County of residence;
(6) Five digit ZIP code;
(7) Alpha numeric patient control number assigned by the hospital for each record (the Visit Identification Number);
(8) Emergency department facility identification number;
(9) Projected payor source;
(10) Date and time of emergency department visit (first documented time);
(11) Mode of transport to the emergency department;
(12) PreMIS identification number, if transported by EMS;
(13) Chief complaint;
(14) Initial temperature reading and route;
(15) Initial systolic and initial diastolic blood pressure;
(16) Triage Notes (brief description of patient's/family's self-reported illness episode, including symptoms, duration of symptoms, and reasons for visit [in addition to Chief Complaint] as presented by the patient or family to the triage nurse upon arrival at the emergency department) – this element is optional;
(17) Initial emergency department acuity assessment;
(18) Coded cause of injury (ICD-9-CM, if injury related to diagnosis);
(19) Emergency department procedures, up to ten (CPT or ICD-9-CM or ICD-10-CM);
(20) Emergency department disposition;
(21) Emergency department disposition diagnosis description; and
(22) Emergency department disposition diagnosis codes, one primary and up to ten additional (ICD-9-CM or ICD-10-CM).

History Note: *Authority G.S. 130A-480;*
Eff. January 1, 2005;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. January 9, 2018.

10A NCAC 41A .0106 REPORTING OF HEALTH CARE-ASSOCIATED INFECTIONS

(a) The following definitions apply throughout this Rule:

(1) "Hospital" means any facility designated as such in G.S. 131E-76(3).
(2) "National Healthcare Safety Network" is an internet-based surveillance system managed by the Centers for Disease Control and Prevention. This system is designed to be used for the direct, standardized reporting of healthcare quality information, including health care-associated infections, by health care facilities to public health entities.
(3) "Health care-associated infection" means a localized or systemic condition in the patient resulting from an adverse reaction to the presence of an infectious agent(s) or its toxin(s) with no evidence that the infection was present or incubating when the patient was admitted to the health care setting.
(4) "Denominator or summary data" refers to referent or baseline data required to generate meaningful statistics for communicating health care-associated infection rates.
(5) "The Centers for Medicaid and Medicare Services - Inpatient Prospective Payment System (CMS – IPPS) rules" are regulations promulgated for the disbursement of operating costs by the Centers for Medicare and Medicaid Services for acute care hospital stays under Medicare Part A based on prospectively set rates for care.

(b) Hospitals shall electronically report all health care-associated infections required by Paragraph (c) of this Rule through the National Healthcare Safety Network and shall make the data available to the Department. Hospitals also shall:

(1) Report all specified health care-associated infections within 30 days following the end of every calendar month during which the infection was identified;
(2) Report all required health care-associated infection denominator or summary data for healthcare-associated infections within 30 days following the end of every calendar month; and,
(3) Comply with all reporting requirements for general participation in the National Healthcare Safety Network.

(c) Except as provided in rules of this Section, hospitals shall report the healthcare-associated infections required by the Centers for Medicare and Medicaid Services listed in the CMS-IPPS rules beginning on the dates specified therein. A summary of the HAI reporting requirements from the current copy of the CMS-IPPS rules may be obtained through the CMS QualityNet site at http://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier2&cid=1228760487021 The CMS IPPS rules themselves can be obtained from the CMS IPPS website at http://www.cms.gov/AcuteInpatientPPS/IPPS2011/list.asp#TopOfPage and http://www.cms.gov/AcuteInpatientPPS/FR2012/list.asp#TopOfPage. A copy of the current CMS-IPPS rules, applicable to this section, is available for inspection in the Division of Public Health, 225 N. McDowell Street, Raleigh NC 27601.

(d) Beginning October 1, 2012 and quarterly thereafter, the Department shall release reports to the public on health care-associated infection(s) in North Carolina.

History Note: *Authority G.S. 130A-150;*
Temporary Adoption Eff. November 30, 2011;
Eff. October 1, 2012;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. January 9, 2018.

10A NCAC 41A .0107 REPORTING OF COVID-19 DIAGNOSTIC TEST RESULTS

(a) For purposes of this Rule, the following definitions shall apply:
(1) "COVID-19 diagnostic test" means any nucleic acid or antigen test that identifies SARS-CoV-2, the virus that causes COVID-19.
(2) "Electronic laboratory reporting" means the automated messaging of laboratory reports sent to the Division of Public Health using a machine-readable electronic communication protocol.
(3) "Healthcare provider" means a healthcare provider as defined in G.S. 130A-476(g).
(4) "Laboratory" means a facility that performs testing on specimens obtained from humans for the purpose of providing information for health assessment and for the diagnosis, prevention, or treatment of disease and is certified by the United States Department of Health and Human Services under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) and implementing regulations. This definition includes a healthcare provider who performs testing in an on-site facility that meets these requirements.

(b) Each person in charge of a laboratory providing diagnostic service in this State shall report the results of all COVID-19 diagnostic tests to the Division of Public Health using electronic laboratory reporting. For purposes of COVID-19, a novel coronavirus under Rule .0101(c)(1) of this Section, the required method of reporting set out in Rules .0101(c) and .0102(d)(3) of this Section shall not apply. The report shall include all of the elements required to be reported under the United States Department of Health and Human Services, laboratory data reporting guidance, which is hereby incorporated by reference, including any subsequent amendments and editions, and available free of charge at https://www.hhs.gov/sites/default/files/covid-19-laboratory-data-reporting-guidance.pdf.

(c) The requirements set forth in Paragraph (b) of this Rule shall be considered met if a laboratory:
(1) submits a COVID-19 Laboratory Data Automation Registration form to the Division of Public Health and acts in good faith to onboard to electronic laboratory reporting. This form shall be submitted within seven calendar days of the date the laboratory starts performing COVID-19 diagnostic testing and shall contain the following elements:
(A) the name, address, phone number, and CLIA number of the laboratory;
(B) the name, address, and phone number of the person in charge of the laboratory or that person's designee;
(C) the type of test performed, testing capacity, and whether the laboratory will use a third-party laboratory to perform part or all of the testing; and

(D) if the laboratory will use a third-party laboratory to perform part or all of the testing, the information in Subparagraphs (c)(1)(A)-(B) for the third-party laboratory; and

(2) until onboarding to electronic laboratory reporting is complete:

(A) reports the results of positive COVID-19 diagnostic tests to the Division of Public Health, including all elements required in Paragraph (b) of this Rule, by secure telefax; and

(B) reports the aggregate number of positive and negative nucleic acid COVID-19 diagnostic tests and the aggregate number of positive and negative antigen COVID-19 diagnostic tests per day to the Division of Public Health through an online survey.

(d) The requirements set forth in Paragraph (b) of this Rule shall be considered met if a laboratory that completes fewer than 50 total COVID-19 diagnostic tests per week submits results as set out in Subparagraph (c)(2) of this Rule.

(e) Healthcare providers who order COVID-19 diagnostic testing in this State shall:

(1) report the results of positive COVID-19 diagnostic tests by secure telefax to the local health director in the county or district where the patient resides. The report shall contain:

(A) patient first and last name, date of birth, address, county of residence, phone number, sex, race, and ethnicity;

(B) provider name, address, phone number, and NPI;

(C) the specimen collection date, the test order date, and the test result date;

(D) the test result; and

(E) all other available elements required in Paragraph (b) of this Rule; and

(2) report the aggregate number of positive and negative nucleic acid COVID-19 diagnostic tests and the aggregate number of positive and negative antigen COVID-19 diagnostic tests per day to the Division of Public Health through an online survey.

(f) The requirements set forth in Paragraph (e) of this Rule shall be considered met if a healthcare provider:

(1) verifies that the laboratory that receives the specimen for testing will report the test result in accordance with Paragraph (b) of this Rule; and

(2) includes patient first and last name, date of birth, address, county of residence, phone number, sex, race, ethnicity, and specimen collection date on the lab order.

(g) The requirement for healthcare providers to report COVID-19 diagnostic test results, as set out in Paragraph (e) of this Rule, is separate from the requirement for physicians to report suspected infections of COVID-19, a novel coronavirus, including positive COVID-19 diagnostic test results, in accordance with G.S. 130A-135 and Rules .0101(a) and .0102(a) of this Section.

(h) Laboratories and healthcare providers who are required to report under this Rule shall report positive COVID-19 diagnostic test results immediately and negative COVID-19 diagnostic test results within 24 hours of receiving the result. Results reported to a local health department under this Rule shall be forwarded to the Division of Public Health within 24 hours of receipt by the local health department.

History Note: *Authority G.S. 130A-134; 130A-135; 130A-139; 130A-141; 130A-141.1; S.L. 2020-4, s. 4.10(a)(1); P.L. 100-578; 42 C.F.R. 493;*
Emergency Adoption Eff. September 25, 2020.

SECTION .0200 - CONTROL MEASURES FOR COMMUNICABLE DISEASES

10A NCAC 41A .0201 CONTROL MEASURES - GENERAL

(a) Except as provided in Rules of this Section, the recommendations and guidelines for testing, diagnosis, treatment, follow-up, and prevention of transmission for each disease and condition specified by the American Public Health Association in its publication, Control of Communicable Diseases Manual shall be the required control measures. Control of Communicable Diseases Manual is hereby incorporated by reference including subsequent amendments and editions. Guidelines and recommended actions published by the Centers for Disease Control and Prevention shall supercede those contained in the Control of Communicable Disease Manual and are likewise incorporated by reference, including subsequent amendments and editions. Copies of the Control of Communicable Diseases Manual may be purchased from the American Public Health Association, Publication Sales Department, Post Office Box 753, Waldora, MD 20604 for a cost of twenty-two dollars ($22.00) each plus five dollars ($5.00) shipping and handling. Copies of Centers for Disease Control and Prevention guidelines contained in the Morbidity and Mortality Weekly Report may be purchased from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402 for a total cost of three dollars and fifty cents ($3.50) each.

Copies of both publications are available for inspection in the Division of Public Health, 1915 Mail Service Center, Raleigh, North Carolina 27699-1915.

(b) In interpreting and implementing the specific control measures adopted in Paragraph (a) of this Rule, and in devising control measures for outbreaks designated by the State Health Director and for communicable diseases and conditions for which a specific control measure is not provided by this Rule, the following principles shall be used:

(1) control measures shall be those which can reasonably be expected to decrease the risk of transmission and which are consistent with recent scientific and public health information;

(2) for diseases or conditions transmitted by the airborne route, the control measures shall require physical isolation for the duration of infectivity;

(3) for diseases or conditions transmitted by the fecal-oral route, the control measures shall require exclusions from situations in which transmission can be reasonably expected to occur, such as work as a paid or voluntary food handler or attendance or work in a day care center for the duration of infectivity;

(4) for diseases or conditions transmitted by sexual or the blood-borne route, control measures shall require prohibition of donation of blood, tissue, organs, or semen, needle-sharing, and sexual contact in a manner likely to result in transmission for the duration of infectivity.

(c) Persons with congenital rubella syndrome, tuberculosis, and carriers of Salmonella typhi and hepatitis B who change residence to a different local health department jurisdiction shall notify the local health director in both jurisdictions.

(d) Isolation and quarantine orders for communicable diseases and communicable conditions for which control measures have been established shall require compliance with applicable control measures and shall state penalties for failure to comply. These isolation and quarantine orders may be no more restrictive than the applicable control measures.

(e) An individual enrolled in an epidemiologic or clinical study shall not be required to meet the provisions of 10A NCAC 41A .0201 - .0209 which conflict with the study protocol if:

(1) the protocol is approved for this purpose by the State Health Director because of the scientific and public health value of the study, and

(2) the individual fully participates in and completes the study.

(f) A determination of significant risk of transmission under this Subchapter shall be made only after consideration of the following factors, if known:

(1) The type of body fluid or tissue;

(2) The volume of body fluid or tissue;

(3) The concentration of pathogen;

(4) The virulence of the pathogen; and

(5) The type of exposure, ranging from intact skin to non-intact skin, or mucous membrane.

(g) The term "household contacts" as used in this Subchapter means any person residing in the same domicile as the infected person.

History Note: *Authority G.S. 130A-135; 130A-144;*
Temporary Rule Eff. February 1, 1988, for a period of 180 days to expire on July 29, 1988;
Eff. March 1, 1988;
Amended Eff. February 1, 1990; November 1, 1989; August 1, 1988;
Recodified Paragraphs (d), (e) to Rule .0202; Paragraph (i) to Rule .0203 Eff. June 11, 1991;
Amended Eff. April 1, 2003; October 1, 1992; December 1, 1991; August 1, 1998;
Emergency Amendment Eff. January 24, 2005;
Emergency Amendment Expired on April 16, 2005;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. January 9, 2018.

10A NCAC 41A .0202 CONTROL MEASURES – HIV

The following are the control measures for the Human Immunodeficiency Virus (HIV) infection:

(1) Persons diagnosed with HIV infection (hereafter "person living with HIV") shall:

(a) refrain from sexual intercourse unless condoms are used except when:

(i) the person living with HIV is in HIV care, is adherent with the treatment plan of the attending physician, and has been virally suppressed for at least 6 months (HIV levels below 200 copies per milliliter) at the time of sexual intercourse;

(ii) the sexual intercourse partner is HIV positive;
(iii) the sexual intercourse partner is taking HIV Pre-Exposure Prophylaxis (PrEP) – antiretroviral medication used to prevent HIV infection as directed by an attending physician; or
(iv) the sexual intercourse occurred in the context of a sexual assault in which the person living with HIV was the victim;

(b) not share needles or syringes, or any other drug-related equipment, paraphernalia, or works that may be contaminated with blood through previous use;

(c) not donate or sell blood, plasma, platelets, other blood products, semen, ova, tissues, organs, or breast milk, except when:
(i) The person living with HIV is donating organs as part of a clinical research study that has been approved by an institutional review board under the criteria, standards, and regulations described in 42 USC 274f-5(a) and (b);

or, if the United States Secretary of Health and Human Services determines under USC 274f-5(c) that participation in this clinical research is no longer warranted as a requirement for transplants, and the organ recipient is receiving the transplant under the criteria, standards, and regulations of USC 274f-5(c); or
(ii) Sperm or ova are harvested under the supervision of an attending physician to be used by the person's spouse or partner for the purpose of achieving pregnancy.

(d) have a test for tuberculosis;

(e) notify future sexual intercourse partners of the infection, unless the person living with HIV meets the criteria listed in Sub-item (1)(a)(i) of this Rule. If the person living with HIV is the victim of a sexual assault, there is no requirement to notify the assailant;

(f) if the time of initial infection is known, notify persons who have been sexual intercourse or needle-sharing partners since the date of infection or give the names to a disease intervention specialist employed by the local health department or by the Division of Public Health for contact tracing and notification; and

(g) if the date of initial infection is unknown, notify persons who have been sexual intercourse or needle-sharing partners for the previous 12 months or give names to a disease intervention specialist employed by the local health department or by the Division of Public Health for contact tracing of all sexual and needle-sharing partners for the preceding 12 months.

(2) The attending physician shall:

(a) give the control measures in Item (1) of this Rule to patients living with HIV in accordance with 10A NCAC 41A .0210;

(b) advise persons living with HIV to notify all future sexual partners of infection;

(c) If the attending physician knows the identity of the spouse of the person living with HIV and has not, with the consent of the person living with HIV, notified and counseled the spouse, the physician shall list the spouse on a form provided by the Division of Public Health and shall send the form to the Division by secure transmission, required by 45 CFR 164.312(e)(1), or by secure fax at (919) 715-4699. The Division shall undertake to counsel the spouse and the attending physician's responsibility to notify exposed and potentially exposed persons shall be satisfied by fulfilling the requirements of Sub-Items (2)(a) and (c) of this Rule;

(d) advise persons living with HIV concerning proper methods for the clean-up of blood and other body fluids;

(e) advise persons living with HIV concerning the risk of perinatal transmission and transmission by breastfeeding.

(3) The attending physician of a child living with HIV who may pose a significant risk of transmission in the school or day care setting because of open, oozing wounds or because of behavioral abnormalities shall notify the local health director. The local health director shall consult with the attending physician and investigate the following circumstances:

(a) If the child is in school or scheduled for admission and the local health director determines that there may be a significant risk of transmission, the local health director shall consult with an interdisciplinary committee, which shall include school personnel, a medical expert, and the child's parents or legal guardians to assist in the investigation and

determination of risk. The local health director shall notify the superintendent or private school director of the need to appoint this interdisciplinary committee. Significant risk of transmission shall be determined in accordance with the HIV Risk and Prevention Estimates published by the Centers for Disease Control and Prevention, which are hereby incorporated by reference including subsequent amendments and editions. A copy of this publication can be accessed at no cost online at https://www.cdc.gov/hiv/risk/estimates/riskbehaviors.html.

(i) If the superintendent or private school director establishes this committee within three days of notification, the local health director shall consult with this committee.

(ii) If the superintendent or private school director does not establish this committee within three days of notification, the local health director shall establish this committee.

(b) If the child is in school or scheduled for admission and the local health director determines, after consultation with the committee, that a significant risk of transmission exists, the local health director shall:

(i) notify the parents or legal guardians;

(ii) notify the committee;

(iii) assist the committee in determining whether an adjustment can be made to the student's school program to eliminate significant risks of transmission;

(iv) determine if an alternative educational setting is necessary to protect the public health;

(v) instruct the superintendent or private school director concerning protective measures to be implemented in the alternative educational setting developed by school personnel; and

(vi) consult with the superintendent or private school director to determine which school personnel directly involved with the child need to be notified of the HIV infection in order to prevent transmission and ensure that these persons are instructed regarding the necessity for protecting confidentiality.

(c) If the child is in day care and the local health director determines that there is a significant risk of transmission, the local health director shall notify the parents or legal guardians that the child must be placed in an alternate child care setting that eliminates the significant risk of transmission.

(4) When health care workers or other persons have a needlestick or nonsexual non-intact skin or mucous membrane exposure to blood or body fluids that, if the source were HIV positive, would pose a significant risk of HIV transmission, the following shall apply:

(a) When the source person is known:

(i) The attending physician or occupational health care provider responsible for the exposed person, if other than the attending physician of the person whose blood or body fluids is the source of the exposure, shall notify the attending physician of the source that an exposure has occurred. The attending physician of the source person shall discuss the exposure with the source and, unless the source is already known to be living with HIV, shall test the source for HIV infection with or without consent unless it reasonably appears that the test cannot be performed without endangering the safety of the source person or the person administering the test. If the source person cannot be tested, any existing specimen shall be tested. The attending physician of the source person shall notify the attending physician of the exposed person of the infection status of the source.

(ii) The attending physician of the exposed person shall inform the exposed person about the infection status of the source, offer testing for HIV infection as soon as possible after exposure and at reasonable intervals until the interval since last exposure is sufficient to assure detection using current CDC HIV testing guidelines, and, if the source person was HIV positive, give the exposed person the control measures listed in Sub-Items (1)(a) through (c) of this Rule. The CDC HIV testing guidelines are hereby incorporated by reference including

subsequent amendments and editions. The CDC HIV testing guidelines can be accessed at no cost online at https://www.cdc.gov/hiv/guidelines/testing.html, with the most current updates found at https://stacks.cdc.gov/view/cdc/23447. The attending physician of the exposed person shall instruct the exposed person regarding the necessity for protecting confidentiality of the source person's HIV status.

(b) When the source person is unknown, the attending physician of the exposed persons shall inform the exposed person of the risk of transmission and offer testing for HIV infection as soon as possible after exposure and at reasonable intervals until the interval since the last exposure is sufficient to assure detection using the current CDC HIV testing guidelines.

(c) A health care facility may release the name of the attending physician of a source person upon request of the attending physician of an exposed person.

(5) The attending physician shall notify the local health director when the physician has cause to suspect a patient living with HIV is not following or cannot follow control measures and is thereby causing a significant risk of transmission. Any other person may notify the local health director when the person has cause to suspect a person living with HIV is not following control measures and is thereby causing a significant risk of transmission.

(6) When the local health director is notified pursuant to Item (5) of this Rule of a person who is mentally ill or intellectually impaired, the local health director shall confer with the attending mental health physician or Local Management Entity/Managed Care Organization and the physician, if any, who notified the local health director to develop a plan to prevent transmission.

(7) The Division of Public Health shall notify the Director of Health Services of the North Carolina Department of Public Safety and the prison facility administrator when any person confined in a state prison is determined to be living with HIV. If the prison facility administrator, in consultation with the Director of Health Services, determines that a confined person living with HIV is not following or cannot follow prescribed control measures, thereby presenting a significant risk of HIV transmission, the administrator and the Director shall develop and implement jointly a plan to prevent transmission, including making recommendations to the unit housing classification committee.

(8) The local health director shall ensure that the health plan for local jails include education of jail staff and prisoners about HIV, how it is transmitted, and how to avoid acquiring or transmitting this infection.

(9) Local health departments shall provide counseling and testing for HIV infection at no charge to the patient. Third party payers may be billed for HIV counseling and testing when such services are provided and the patient provides written consent.

(10) HIV pre-test counseling is not required. Post-test counseling for persons i living with HIV is required, must be individualized, and shall include referrals for medical and psychosocial services and control measures counseling.

(11) Notwithstanding Rule .0201(d) of this Section, a local or state health director may require, as a part of an isolation order issued in accordance with G.S. 130A-145, compliance with a plan to assist the individual to comply with control measures. The plan shall be designed to meet the specific needs of the individual including linkage to care and may include referral to one or more of the following available and appropriate services:

(a) substance abuse counseling and treatment;

(b) harm reduction services;

(c) mental health counseling and treatment required to prevent transmission;

(d) education and counseling sessions about HIV, HIV transmission, and behavior change required to prevent transmission; and

(e) intimate partner violence intervention services.

(12) The Division of Public Health shall conduct a partner notification program to assist in the notification and counseling of partners of persons living with HIV.

(13) Every pregnant woman shall be offered HIV testing by her attending physician at her first prenatal visit and in the third trimester. The attending physician shall test the pregnant woman for HIV infection, unless the pregnant woman refuses to provide informed consent pursuant to G.S. 130A-148(h). If there is no record at labor and delivery of an HIV test result during the current

pregnancy for the pregnant woman, the attending physician shall inform the pregnant woman that an HIV test will be performed, explain the reasons for testing, and the woman shall be tested for HIV without consent using a rapid HIV test unless it reasonably appears to the clinician that the test cannot be performed without endangering the safety of the pregnant woman or the person administering the test. If the pregnant woman cannot be tested, an existing specimen, if one exists that was collected within the last 24 hours, shall be tested using a rapid HIV test. The attending physician must provide the woman with the test results as soon as possible.

(14) If an infant is delivered by a woman with no record of the result of an HIV test conducted during the pregnancy and if the woman was not tested for HIV during labor and delivery, the fact that the mother has not been tested creates a reasonable suspicion pursuant to G.S. 130A-148(h) that the newborn has HIV infection and the infant shall be tested for HIV. An infant born in the previous 12 hours shall be tested using a rapid HIV test

(15) Testing for HIV may be offered as part of routine laboratory testing panels using a general consent that is obtained from the patient for treatment and routine laboratory testing, so long as the patient is notified that they are being tested for HIV and given the opportunity to refuse.

History Note: *Authority G.S. 130A-135; 130A-144; 130A-145; 130A-148(h);*
Temporary Rule Eff. February 1, 1988, for a period of 180 days to expire on July 29, 1988;
Eff. March 1, 1988;
Amended Eff. February 1, 1990; November 1, 1989; June 1, 1989;
Temporary Amendment Eff. January 7, 1991 for a period of 180 days to expire on July 6, 1991;
Amended Eff. May 1, 1991;
Recodified from 15A NCAC 19A .0201 (d) and (e) Eff. June 11, 1991;
Amended Eff. August 1, 1995; October 1, 1994; January 4, 1994; October 1, 1992;
Temporary Amendment Eff. February 18, 2002; June 1, 2001;
Amended Eff. January 1, 2018; November 1, 2007; April 1, 2005; April 1, 2003;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. January 9, 2018.

10A NCAC 41A .0203 CONTROL MEASURES - HEPATITIS B

(a) The following are the control measures for hepatitis B infection. The infected persons shall:

(1) refrain from sexual intercourse unless condoms are used except when the partner is known to be infected with or immune to hepatitis B;

(2) not share needles or syringes;

(3) not donate or sell blood, plasma, platelets, other blood products, semen, ova, tissues, organs, or breast milk;

(4) if the time of initial infection is known, identify to the local health director all sexual intercourse and needle partners since the date of infection; and, if the date of initial infection is unknown, identify persons who have been sexual intercourse or needle partners during the previous six months;

(5) for the duration of the infection, notify future sexual intercourse partners of the infection and refer them to their attending physician or the local health director for control measures; and for the duration of the infection, notify the local health director of all new sexual intercourse partners;

(6) identify to the local health director all current household contacts;

(7) be tested six months after diagnosis to determine if they are chronic carriers, and when necessary to determine appropriate control measures for persons exposed pursuant to Paragraph (b) of this Rule;

(8) comply with all control measures for hepatitis B infection specified in Paragraph (a) of 10A NCAC 41A .0201, in those instances where such control measures do not conflict with other requirements of this Rule.

(b) The following are the control measures for persons reasonably suspected of being exposed:

(1) when a person has had a sexual intercourse exposure to hepatitis B infection, the person shall be tested;

(2) after testing, when a susceptible person has had sexual intercourse exposure to hepatitis B infection, the person shall be given a dose appropriate for body weight of hepatitis B immune

globulin and hepatitis B vaccination as soon as possible; hepatitis B immune globulin shall be given no later than two weeks after the last exposure;

(3) when a person is a household contact, sexual intercourse or needle sharing contact of a person who has remained infected with hepatitis B for six months or longer, the partner or household contact, if susceptible and at risk of continued exposure, shall be vaccinated against hepatitis B;

(4) when a health care worker or other person has a needlestick, non-intact skin, or mucous membrane exposure to blood or body fluids that, if the source were infected with the hepatitis B virus, would pose a significant risk of hepatitis B transmission, the following shall apply:

(A) when the source is known, the source person shall be tested for hepatitis B infection, unless already known to be infected;

(B) when the source is infected with hepatitis B and the exposed person is:

(i) vaccinated, the exposed person shall be tested for anti-HBs and, if anti-HBs is unknown or less than 10 milli-International Units per ml, receive hepatitis B vaccination and hepatitis B immune globulin as soon as possible; hepatitis B immune globulin shall be given no later than seven days after exposure;

(ii) not vaccinated, the exposed person shall be given a dose appropriate for body weight of hepatitis B immune globulin immediately and begin vaccination with hepatitis B vaccine within seven days;

(C) when the source is unknown, the determination of whether hepatitis B immunization is required shall be made in accordance with current published Control of Communicable Diseases Manual and Centers for Disease Control and Prevention guidelines. Copies of the Control of Communicable Diseases Manual may be purchased from the American Public Health Association, Publication Sales Department, Post Office Box 753, Waldora, MD 20604 for a cost of twenty-two dollars ($22.00) each plus five dollars ($5.00) shipping and handling. Copies of Center for Disease Control and Prevention guidelines contained in the Morbidity and Mortality Weekly Report may be purchased from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402 for a cost of three dollars fifty cents ($3.50) each. Copies of both publications are available for inspection in the General Communicable Disease Control Branch, Cooper Memorial Health Building, 225 N. McDowell Street, Raleigh, North Carolina 27603-1382.

(5) infants born to HBsAg-positive mothers shall be given hepatitis B vaccination and hepatitis B immune globulin within 12 hours of birth or as soon as possible after the infant is stabilized. Additional doses of hepatitis B vaccine shall be given in accordance with current published Control of Communicable Diseases Manual and Centers for Disease Control and Prevention Guidelines. The infant shall be tested for the presence of HBsAg and anti-HBs within three to nine months after the last dose of the regular series of vaccine; if required because of failure to develop immunity after the regular series, additional doses shall be given in accordance with current published Control of Communicable Diseases Manual and Centers for Disease Control and Prevention guidelines. Copies of the Control of Communicable Diseases Manual may be purchased from the American Public Health Association, Publication Sales Department, Post Office Box 753, Waldora, MD 20604 for a cost of twenty-two dollars ($22.00) each plus five dollars ($5.00) shipping and handling. Copies of Center for Disease Control and Prevention guidelines contained in the Morbidity and Mortality Weekly Report may be purchased from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402 for a cost of three dollars fifty cents ($3.50) each. Copies of both publications are available for inspection in the General Communicable Disease Control Branch, Cooper Memorial Health Building, 225 N. McDowell Street, Raleigh, North Carolina 27603-1382;

(6) infants born to mothers whose HBsAg status is unknown shall be given hepatitis B vaccine within 12 hours of birth and the mother tested. If the tested mother is found to be HBsAg-positive, the infant shall be given hepatitis B immune globulin as soon as possible and no later than seven days after birth;

(7) when an acutely infected person is a primary caregiver of a susceptible infant less than 12 months of age, the infant shall receive an appropriate dose of hepatitis B immune globulin and hepatitis vaccinations in accordance with current published Control of Communicable Diseases Manual and Centers for Disease Control and Prevention Guidelines. Copies of the Control of Communicable

Diseases Manual may be purchased from the American Public Health Association, Publication Sales Department, Post Office Box 753, Waldora, MD 20604 for a cost of twenty-two dollars ($22.00) each plus five dollars ($5.00) shipping and handling. Copies of Center for Disease Control and Prevention guidelines contained in the Morbidity and Mortality Weekly Report may be purchased from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402 for a cost of three dollars fifty cents ($3.50) each. Copies of both publications are available for inspection in the General Communicable Disease Control Branch, Cooper Memorial Health Building, 225 N. McDowell Street, Raleigh, North Carolina 27603-1382.

(c) The attending physician shall advise all patients known to be at high risk, including injection drug users, men who have sex with men, hemodialysis patients, and patients who receive multiple transfusions of blood products, that they should be vaccinated against hepatitis B if susceptible. The attending physician shall also recommend that hepatitis B chronic carriers receive hepatitis A vaccine (if susceptible).

(d) The following persons shall be tested for and reported in accordance with 10A NCAC 41A .0101 if positive for hepatitis B infection:

(1) pregnant women unless known to be infected; and

(2) donors of blood, plasma, platelets, other blood products, semen, ova, tissues, or organs.

(e) The attending physician of a child who is infected with hepatitis B virus and who may pose a significant risk of transmission in the school or day care setting because of open, oozing wounds or because of behavioral abnormalities such as biting shall notify the local health director. The local health director shall consult with the attending physician and investigate the circumstances.

(f) If the child referred to in Paragraph (e) of this Rule is in school or scheduled for admission and the local health director determines that there may be a significant risk of transmission, the local health director shall consult with an interdisciplinary committee, which shall include school personnel, a medical expert, and the child's parent or guardian to assist in the investigation and determination of risk. The local health director shall notify the superintendent or private school director of the need to appoint such an interdisciplinary committee. If the superintendent or private school director establishes such a committee within three days of notification, the local health director shall consult with this committee. If the superintendent or private school director does not establish such a committee within three days of notification, the local health director shall establish such a committee.

(g) If the child referred to in Paragraph (e) of this Rule is in school or scheduled for admission and the local health director determines, after consultation with the committee, that a significant risk of transmission exists, the local health director shall:

(1) notify the parents;

(2) notify the committee;

(3) assist the committee in determining whether an adjustment can be made to the student's school program to eliminate significant risks of transmission;

(4) determine if an alternative educational setting is necessary to protect the public health;

(5) instruct the superintendent or private school director concerning protective measures to be implemented in the alternative educational setting developed by school personnel; and

(6) consult with the superintendent or private school director to determine which school personnel directly involved with the child need to be notified of the hepatitis B virus infection in order to prevent transmission and ensure that these persons are instructed regarding the necessity for protecting confidentiality.

(h) If the child referred to in Paragraph (e) of this Rule is in day care and the local health director determines that there is a significant risk of transmission, the local health director shall notify the parents that the child must be placed in an alternate child care setting that eliminates the significant risk of transmission.

History Note: *Authority G.S. 130A-135; 130A-144;*
Eff. February 1, 1990;
Amended Eff. October 1, 1990;
Recodified from 15A NCAC 19A .0201(i) Eff. June 11, 1991;
Amended Eff. August 1, 1998; October 1, 1994;
Temporary Amendment Eff. February 18, 2002;
Amended Eff. April 1, 2003;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. January 9, 2018.

10A NCAC 41A .0204 CONTROL MEASURES - SEXUALLY TRANSMITTED DISEASES

(a) Local health departments shall provide diagnosis, testing, treatment, follow-up, and preventive services for syphilis, gonorrhea, chlamydia, nongonococcal urethritis, mucopurulent cervicitis, chancroid, lymphogranuloma venereum, and granuloma inguinale. These services shall be provided upon request and at no charge to the patient.

(b) Persons infected with, exposed to, or reasonably suspected of being infected with gonorrhea, chlamydia, non-gonococcal urethritis, and mucopurulent cervicitis shall:

(1) Refrain from sexual intercourse until examined and diagnosed and treatment is completed, and all lesions are healed;

(2) Be tested, treated, and re-evaluated in accordance with the STD Treatment Guidelines published by the U.S. Public Health Service. The recommendations contained in the STD Treatment Guidelines are the required control measures for testing, treatment, and follow-up for gonorrhea, chlamydia, nongonococcal urethritis, and mucopurulent cervicitis, and are incorporated by reference including subsequent amendments and editions. A copy of this publication is on file for public viewing with the and a copy may be obtained free of charge by writing the Division of Public Health, 1915 Mail Service Center, Raleigh, North Carolina 27699-1915, and requesting a copy. However, urethral Gram stains may be used for diagnosis of males rather than gonorrhea cultures unless treatment has failed;

(3) Notify all sexual partners from 30 days before the onset of symptoms to completion of therapy that they must be evaluated by a physician or local health department.

(c) Persons infected with, exposed to, or reasonably suspected of being infected with syphilis, lymphogranuloma venereum, granuloma inguinale, and chancroid shall:

(1) Refrain from sexual intercourse until examined and diagnosed and treatment is completed, and all lesions are healed;

(2) Be tested, treated, and re-evaluated in accordance with the STD Treatment Guidelines published by the U.S. Public Health Service. The recommendations contained in the STD Treatment Guidelines are the required control measures for testing, treatment, and follow-up for syphilis, lymphogranuloma venereum, granuloma inguinale, and chancroid, except that chancroid cultures are not required;

(3) Give names to a disease intervention specialist employed by the local health department or by the Division of Public Health for contact tracing of all sexual partners and others as listed in this Rule:

(A) for syphilis:

(i) congenital - parents and siblings;

(ii) primary - all partners from three months before the onset of symptoms to completion of therapy and healing of lesions;

(iii) secondary - all partners from six months before the onset of symptoms to completion of therapy and healing of lesions; and

(iv) latent - all partners from 12 months before the onset of symptoms to completion of therapy and healing of lesions and, in addition, for women with late latent, spouses and children;

(B) for lymphogranuloma venereum:

(i) if there is a primary lesion and no buboes, all partners from 30 days before the onset of symptoms to completion of therapy and healing of lesions; and

(ii) if there are buboes all partners from six months before the onset of symptoms to completion of therapy and healing of lesions;

(C) for granuloma inguinale - all partners from three months before the onset of symptoms to completion of therapy and healing of lesions; and

(D) or chancroid - all partners from ten days before the onset of symptoms to completion of therapy and healing of lesions.

(d) All persons evaluated or reasonably suspected of being infected with any sexually transmitted disease shall be tested for syphilis, encouraged to be tested confidentially for HIV, and counseled about how to reduce the risk of acquiring sexually transmitted disease, including the use of condoms.

(e) All pregnant women shall be tested for syphilis, chlamydia and gonorrhea at the first prenatal visit. All pregnant women shall be tested for syphilis between 28 and 30 weeks of gestation and at delivery. Hospitals shall determine the syphilis serologic status of the mother prior to discharge of the newborn so that if necessary the newborn can be

evaluated and treated as provided in (c)(2) of this rule. Pregnant women 25 years of age and younger shall be tested for chlamydia and gonorrhea in the third trimester or at delivery if the woman was not tested in the third trimester.
(f) Any woman who delivers a stillborn infant shall be tested for syphilis.
(g) All newborn infants shall be treated prophylactically against gonococcal ophthalmia neonatorum in accordance with the STD Treatment Guidelines published by the U.S. Public Health Service. The recommendations contained in the STD Treatment Guidelines are the required prophylactic treatment against gonococcal ophthalmia neonatorum.

History Note: *Authority G. S. 130A-135; 130A-144;*
Eff. December 1, 1991;
Amended Eff. April 1, 2008; November 1, 2007; April 1, 2003; July 1, 1993;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. January 9, 2018.

10A NCAC 41A .0205 CONTROL MEASURES – TUBERCULOSIS
(a) The local health director shall investigate all cases of tuberculosis disease and their contacts in accordance with recommendations and guidelines published by the Centers for Disease Control and Prevention which are hereby incorporated by reference including subsequent amendments and editions. The recommendations and guidelines are the required control measures for tuberculosis, except as otherwise provided in this Rule. A copy of the recommendations and guidelines is available by contacting the Division of Public Health, 1931 Mail Service Center, Raleigh, North Carolina 27699-1931 or by accessing the Centers for Disease Control and Prevention website at http://www.cdc.gov/tb.
(b) The following persons shall have a tuberculin skin test (TST) or Interferon Gamma Release Assay (IGRA) administered in accordance with recommendations and guidelines published by the Centers for Disease Control and Prevention:

(1) Household and other high priority contacts of active cases of pulmonary and laryngeal tuberculosis. For purposes of this Rule, a high priority contact is defined in accordance with Centers for Disease Control and Prevention guidelines. If the contact's initial skin or IGRA test is negative, and the case is confirmed by culture, a repeat skin or IGRA test shall be performed 8 to 10 weeks after the exposure has ended;
(2) Persons reasonably suspected of having tuberculosis disease;
(3) Inmates in the custody of the Department of Public Safety, Division of Adult Correction upon incarceration, and annually thereafter;
(4) Persons with HIV infection or AIDS.

(c) The following persons shall be tested using a two-step skin test method or a single IGRA test, administered in accordance with recommendations and guidelines published by the Centers for Disease Control and Prevention:

(1) Staff with direct inmate contact in the Department of Public Safety, Division of Adult Correction upon employment;
(2) Staff of licensed nursing homes or adult care homes upon employment;
(3) Residents upon admission to licensed nursing homes or adult care homes. If the individual is being admitted directly from another hospital, licensed nursing home or adult care home in North Carolina and there is documentation of a two-step skin test or a single IGRA test, the individual does not need to be retested;
(4) Staff in adult day care centers providing care for persons with HIV infection or AIDS upon employment.

(d) Except as provided in the last sentence of Subparagraph (c)(3) of this Rule, persons listed in Paragraph (c) of this rule shall be required only to have a single TST or IGRA in the following situations:

(1) If the person has ever had a two-step skin test; or
(2) If the person has had a single skin test within the last twelve months.

(e) Persons with a positive tuberculin skin test or IGRA shall be evaluated by an interview to screen for symptoms and a chest x-ray if they do not have a documented chest x-ray that was performed on the date of the positive test or later.
(f) Treatment and follow-up for tuberculosis infection or disease shall be in accordance with the recommendations and guidelines from the Centers for Disease Control and Prevention.
(g) Persons with active tuberculosis disease shall complete a standard multi-drug regimen, and shall be managed using Directly Observed Therapy (DOT), which is the actual observation of medication ingestion by a health care worker (HCW).

If a standard multi-drug regimen cannot be used, the attending physician shall consult with the state Tuberculosis Medical Director or designee on the treatment plan.

(h) Persons with suspected or known active pulmonary or laryngeal tuberculosis who have sputum smears positive for acid fast bacilli shall be considered infectious and shall be managed using airborne precautions including respiratory isolation or isolation in their home with no new persons exposed. These individuals are considered noninfectious and use of airborne precautions, precautions including respiratory isolation or isolation in their home may be discontinued when:

(1) Sputum specimen results meet Centers for Disease Control and Prevention criteria for discontinuation of respiratory isolation;
(2) They have two consecutive sputum smears collected at least eight hours apart which are negative;
(3) It has been at least seven days since the last positive sputum smear; and
(4) They have been compliant on tuberculosis medications to which the organism is susceptible and there is evidence of clinical response to tuberculosis treatment.

(i) Persons with suspected or known active pulmonary or laryngeal tuberculosis who are initially sputum smear negative require respiratory isolation until they have been started on tuberculosis treatment to which the organism is susceptible and there is evidence of clinical response to treatment.

History Note: *Authority G.S. 130A-135; 130A-144;*
Eff. March 1, 1992;
Amended Eff. April 1, 2006; April 1, 2003; August 1, 1998; October 1, 1994;
Temporary Amendment Eff. August 1, 2011;
Amended Eff. July 1, 2012;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. January 9, 2018.

10A NCAC 41A .0206 INFECTION PREVENTION – HEALTH CARE SETTINGS

(a) The following definitions apply throughout this Rule:

(1) "Health care organization" means a hospital; clinic; physician, dentist, podiatrist, optometrist, or chiropractic office; home care agency; nursing home; local health department; community health center; mental health facility; hospice; ambulatory surgical facility; urgent care center; emergency room; Emergency Medical Service (EMS) agency; pharmacies where a health practitioner offers clinical services; or any other organization that provides clinical care.
(2) "Invasive procedure" means entry into tissues, cavities, or organs or repair of traumatic injuries. The term includes the use of needles to puncture skin, vaginal and cesarean deliveries, surgery, and dental procedures during which bleeding occurs or the potential for bleeding exists.
(3) "Non-contiguous" means not physically connected.

(b) In order to prevent transmission of HIV, hepatitis B, hepatitis C and other bloodborne pathogens each health care organization that performs invasive procedures shall implement a written infection control policy. The health care organization shall ensure that health care workers in its employ or who have staff privileges are trained in the principles of infection control and the practices required by the policy; require and monitor compliance with the policy; and update the policy as needed to prevent transmission of HIV, hepatitis B, hepatitis C and other bloodborne pathogens. The health care organization shall designate one on-site staff member for each noncontiguous facility to direct these activities. The designated staff member in each health care facility shall complete a course in infection control approved by the Department. The Department shall approve a course that addresses:

(1) Epidemiologic principles of infectious disease;
(2) Principles and practice of asepsis;
(3) Sterilization, disinfection, and sanitation;
(4) Universal blood and body fluid precautions;
(5) Safe injection practices;
(6) Engineering controls to reduce the risk of sharp injuries;
(7) Disposal of sharps; and
(8) Techniques that reduce the risk of sharp injuries to health care workers.

(c) The infection control policy required by this Rule shall address the following components that are necessary to prevent transmission of HIV, hepatitis B, hepatitis C and other bloodborne pathogens:

(1) Sterilization and disinfection, including a schedule for maintenance and microbiologic monitoring of equipment; the policy shall require documentation of maintenance and monitoring;

(2) Sanitation of rooms and equipment, including cleaning procedures, agents, and schedules;
(3) Accessibility of infection control devices and supplies; and
(4) Procedures to be followed in implementing 10A NCAC 41A .0202(4) and .0203(b)(4) when a health care provider or a patient has an exposure to blood or other body fluids of another person in a manner that poses a significant risk of transmission of HIV or hepatitis B.

(d) Health care workers and emergency responders shall, with all patients, follow Centers for Disease Control and Prevention Guidelines on blood and body fluid precautions incorporated by reference in 10A NCAC 41A .0201.

(e) Health care workers who have exudative lesions or weeping dermatitis shall refrain from handling patient care equipment and devices used in performing invasive procedures and from all direct patient care that involves the potential for contact of the patient, equipment, or devices with the lesion or dermatitis until the condition resolves.

(f) All equipment used to puncture skin, mucous membranes, or other tissues in medical, dental, or other settings must be disposed of in accordance with 15A NCAC 13B .1200 after use or sterilized prior to reuse.

History Note: *Authority G.S. 130A-144; 130A-145; 130A-147;*
Eff. October 1, 1992;
Amended Eff. January 1, 2010; December 1, 2003; July 1, 1994; January 4, 1994;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. January 9, 2018.

10A NCAC 41A .0207 HIV AND HEPATITIS B INFECTED HEALTH CARE WORKERS

(a) The following definitions shall apply throughout this Rule:
(1) "Surgical or obstetrical procedures" means vaginal deliveries or surgical entry into tissues, cavities, or organs. The term does not include phlebotomy; administration of intramuscular, intradermal, or subcutaneous injections; needle biopsies; needle aspirations; lumbar punctures; angiographic procedures; endoscopic and bronchoscopic procedures; or placing or maintaining peripheral or central intravascular lines.
(2) "Dental procedure" means any dental procedure involving manipulation, cutting, or removal of oral or perioral tissues, including tooth structure during which bleeding occurs or the potential for bleeding exists. The term does not include the brushing of teeth.

(b) All health care workers who perform surgical or obstetrical procedures or dental procedures and who know themselves to be infected with HIV or hepatitis B shall notify the State Health Director. Health care workers who assist in these procedures in a manner that may result in exposure of patients to their blood and who know themselves to be infected with HIV or hepatitis B shall also notify the State Health Director. The notification shall be made in writing to the Chief, Communicable Disease Control Branch, 1902 Mail Service Center, Raleigh, NC 27699-1902..

(c) The State Health Director shall investigate the practice of any infected health care worker and the risk of transmission to patients. The investigation may include review of medical and work records and consultation with health care professionals who may have information necessary to evaluate the clinical condition or practice of the infected health care worker. The attending physician of the infected health care worker shall be consulted. The State Health Director shall protect the confidentiality of the infected health care worker and may disclose the worker's infection status only when essential to the conduct of the investigation or periodic reviews pursuant to Paragraph (h) of this Rule. When the health care worker's infection status is disclosed, the State Health Director shall give instructions regarding the requirement for protecting confidentiality.

(d) If the State Health Director determines that there may be a significant risk of transmission of HIV or hepatitis B to patients, the State Health Director shall appoint an expert panel to evaluate the risk of transmission to patients, and review the practice, skills, and clinical condition of the infected health care worker, as well as the nature of the surgical or obstetrical procedures or dental procedures performed and operative and infection control techniques used. Each expert panel shall include an infectious disease specialist, an infection control expert, a person who practices the same occupational specialty as the infected health care worker and, if the health care worker is a licensed professional, a representative of the appropriate licensure board. The panel may include other experts. The State Health Director shall consider for appointment recommendations from health care organizations and local societies of health care professionals.

(e) The expert panel shall review information collected by the State Health Director and may request that the State Health Director obtain additional information as needed. The State Health Director shall not reveal to the panel the identity of the infected health care worker. The infected health care worker and the health care worker's attending

physician shall be given an opportunity to present information to the panel. The panel shall make recommendations to the State Health Director that address the following:

(1) Restrictions that are necessary to prevent transmission from the infected health care worker to patients;

(2) Identification of patients that have been exposed to a significant risk of transmission of HIV or hepatitis B; and

(3) Periodic review of the clinical condition and practice of the infected health care worker.

(f) If, prior to receipt of the recommendations of the expert panel, the State Health Director determines that immediate practice restrictions are necessary to prevent an imminent threat to the public health, the State Health Director shall issue an isolation order pursuant to G.S. 130A-145. The isolation order shall require cessation or modification of some or all surgical or obstetrical procedures or dental procedures to the extent necessary to prevent an imminent threat to the public health. This isolation order shall remain in effect until an isolation order is issued pursuant to Paragraph (g) of this Rule or until the State Health Director determines the imminent threat to the public health no longer exists.

(g) After consideration of the recommendations of the expert panel, the State Health Director shall issue an isolation order pursuant to G.S. 130A-145. The isolation order shall require any health care worker who is allowed to continue performing surgical or obstetrical procedures or dental procedures to, within a time period specified by the State Health Director, successfully complete a course in infection control procedures approved by the Department of Health and Human Services, General Communicable Disease Control Branch, in accordance with 10A NCAC 41A .0206(e). The isolation order shall require practice restrictions, such as cessation or modification of some or all surgical or obstetrical procedures or dental procedures, to the extent necessary to prevent a significant risk of transmission of HIV or hepatitis B to patients. The isolation order shall prohibit the performance of procedures that cannot be modified to avoid a significant risk of transmission. If the State Health Director determines that there has been a significant risk of transmission of HIV or hepatitis B to a patient, the State Health Director shall notify the patient or assist the health care worker to notify the patient.

(h) The State Health Director shall request the assistance of one or more health care professionals to obtain information needed to periodically review the clinical condition and practice of the infected health care worker who performs or assists in surgical or obstetrical procedures or dental procedures.

(i) An infected health care worker who has been evaluated by the State Health Director shall notify the State Health Director prior to a change in practice involving surgical or obstetrical procedures or dental procedures. The infected health care worker shall not make the proposed change without approval from the State Health Director. If the State Health Director makes a determination in accordance with Paragraph (c) of this Rule that there is a significant risk of transmission of HIV or hepatitis B to patients, the State Health Director shall appoint an expert panel in accordance with Paragraph (d) of this Rule. Otherwise, the State Health Director shall notify the health care worker that he or she may make the proposed change in practice.

(j) If practice restrictions are imposed on a licensed health care worker, a copy of the isolation order shall be provided to the appropriate licensure board. The State Health Director shall report violations of the isolation order to the appropriate licensure board. The licensure board shall report to the State Health Director any information about the infected health care worker that may be relevant to the risk of transmission of HIV or hepatitis B to patients.

History Note: *Authority G.S. 130A-144; 130A-145;*
Eff. October 1, 1992;
Amended Eff. April 1, 2003;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. January 9, 2018.

10A NCAC 41A .0208 CONTROL MEASURES -- SMALLPOX; VACCINIA DISEASE

(a) Guidelines and recommended actions for prevention of the spread of smallpox and for prevention of the spread of vaccinia published by the Center for Disease Control and Prevention (CDC) shall supercede those contained in the control of Communicable Disease Manual and are incorporated by reference, including subsequent amendments and editions. Copies of CDC guidelines contained in the Morbidity and Mortality weekly reports may be purchased from the Superintendent of Documents, US Government Printing Office, Washington DC 20402 for a total cost of three dollars and fifty cents ($3.50) each.

(b) The attending physician of a person vaccinated against smallpox shall report to the local health department the existence of any of the following:

(1) autoinnoculation;

(2) generalized vaccinia;
(3) eczema vaccinatum;
(4) progressive vaccinia; and
(5) post vaccination encephalitis.

The attending physician shall make the report to the local health department within 24 hours. The local health department shall notify the Division of Public Health within 24 hours.

(c) The physician responsible for vaccinating a person against smallpox and the physician diagnosing a person with vaccinia disease shall instruct the patient to follow CDC guidelines for the prevention of the spread of vaccinia adopted by reference in Paragraph (a) of this Rule. The patient shall follow these guidelines.

(d) The State Health Director or a local health director may use isolation authority pursuant to G.S. 130A-145 when necessary to prevent the spread of smallpox or vaccinia virus.

History Note: *Authority G.S. 130A-144;*
Temporary Adoption Eff. February 13, 2003;
Eff. August 1, 2004;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. January 9, 2018.

10A NCAC 41A .0209 LABORATORY TESTING

All laboratories shall do the following:

(1) When Neisseria meningitidis is isolated from a normally sterile site, test the organism for specific serogroup or send the isolate to the State Laboratory of Public Health for serogrouping;
(2) When a stool culture is requested on a specimen from a person with bloody diarrhea, culture the stool for shiga-toxin producing Escherichia coli or send the specimen to the State Laboratory of Public Health;
(3) When Haemophilus influenzae is isolated, test the organism for specific serogroup or send the isolate to the State Laboratory of Public Health for serogrouping; and
(4) When Mycobacterium tuberculosis complex is isolated, test the organism for specific restriction fragment length polymorphism (RFLP) or send the isolate, or a subculture of the isolate, to the State Laboratory of Public Health for genotyping.

History Note: *Authority G.S. 130A-139;*
Eff. October 1, 1994;
Temporary Amendment Eff. February 18, 2002;
Amended Eff. April 1, 2004; April 1, 2003;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. January 9, 2018.

10A NCAC 41A .0210 DUTIES OF ATTENDING PHYSICIANS

Immediately upon making a diagnosis of or reasonably suspecting a communicable disease or communicable condition for which control measures are provided in Rule .0201, .0202 or .0203 of this Section, the attending physician shall instruct the patient and any other person specified in those control measures to carry out those control measures and shall give sufficiently detailed instructions for proper compliance, or the physician shall request the local health director to give such instruction. When making the initial telephone report for diseases and conditions required to be reported within 24 hours, the physician shall inform the local health director of the control measures given.

History Note: *Authority G.S. 130A-144;*
Temporary Rule Eff. February 1, 1988, for a period of 180 days to expire on July 29, 1988;
Eff. March 1, 1988;
Recodified from 15A NCAC 19A .0202 Eff. June 11, 1991;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. January 9, 2018.

10A NCAC 41A .0211 DUTIES OF OTHER PERSONS

(a) The local health director may reveal the identity and diagnosis of a person with a reportable communicable disease or communicable condition or other communicable disease or communicable condition which represents a significant threat to the public health to those persons specified in Paragraph (b) when disclosure is necessary to prevent transmission in the facility or establishment for which they are responsible. The local health director shall ensure that all persons so notified are instructed regarding the necessity for protecting confidentiality.
(b) The following persons shall require that any person about whom they are notified pursuant to Paragraph (a) comply with control measures given by the local health director to prevent transmission in the facility or establishment:

(1) the principal of any private or public school;
(2) employers;
(3) superintendents or directors of all public or private institutions, hospitals, or jails; and
(4) operators of a child day care center, child day care home, or other child care providers.

(c) The provisions of Paragraphs (a) and (b) shall not apply with regard to gonorrhea, syphilis, chancroid, granuloma inguinale, lymphogranuloma venereum, chlamydia, non-gonococcal urethritis, AIDS, and HIV infection. However, persons may be notified with regard to these diseases and conditions in accordance with 10A NCAC 41A .0201, .0202 or .0203 of this Section.

History Note: *Authority G.S. 130A-143; 130A-144;*
Temporary Rule Eff. February 1, 1988, for a period of 180 days to expire on July 29, 1988;
Eff. March 1, 1988;
Amended Eff. June 1, 1989;
Recodified from 15A NCAC 19A .0203 Eff. June 11, 1991;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. January 9, 2018.

10A NCAC 41A .0212 HANDLING AND TRANSPORTATION OF BODIES

(a) Persons handling the body of any person who has died shall comply with the standard precautions for all patient care published by the United States Centers for Disease Control and Prevention, which are hereby incorporated by reference, including any subsequent amendments and editions, and available free of charge at: https://www.cdc.gov/infectioncontrol/basics/standard-precautions.html.
(b) It shall be the duty of the physician, physician assistant, or nurse practitioner attending to any person who dies and is known to be infected with HIV, plague, hepatitis B, or COVID-19 or any person who dies and is known or reasonably suspected to be infected with smallpox, rabies, severe acute respiratory syndrome (SARS), or Jakob-Creutzfeldt to provide written, verbal, or electronic notification to individuals handling the body of the proper precautions to prevent infection. This written, verbal, or electronic notification shall be provided to the funeral service director, funeral service worker, or body transporter at the time the body is removed from any hospital, nursing home, or other health care facility. When the patient dies in a location other than a health care facility, the physician, physician assistant, or nurse practitioner shall notify the funeral service director, funeral service worker, or body transporter of the precautions required as soon as the physician, physician assistant, or nurse practitioner becomes aware of the death. These precautions are noted in Paragraphs (d), (e), and (f) of this Rule. The duty to notify shall be considered met if performed by one of the following individuals: the physician, physician assistant, or nurse practitioner attending to the person who died or a designated representative of the physician, physician assistant, or nurse practitioner.
(c) It shall also be the duty of a medical examiner with jurisdiction pursuant to G.S. 130A-383 over the body of any person who dies and is known to be infected with COVID-19 to provide written, verbal, or electronic notification to the funeral service director, funeral service worker, or body transporter at the time the body is removed from medical examiner custody of the proper precautions to prevent infection. These precautions are noted in Paragraph (f) of this Rule. The duty to notify shall be considered met if performed by a designated representative of the medical examiner.
(d) The body of any person who died and is known or reasonably suspected to be infected with smallpox or severe acute respiratory syndrome (SARS) or any person who died and is known to be infected with plague shall not be embalmed. The body shall be enclosed in a strong, tightly sealed outer case which will prevent leakage or escape of odors as soon as possible after death and before the body is removed from the hospital room, home, building, or other premises where the death occurred. This case shall not be reopened except with the consent of the local health director. Nothing in this Paragraph shall prohibit cremation.

(e) Persons handling the body of any person who died and is known to be infected with HIV or hepatitis B or any person who died and is known or reasonably suspected to be infected with Jakob-Creutzfeldt or rabies shall be provided written, verbal, or electronic notification to observe blood and body fluid precautions.
(f) Persons handling the body of any person who died and is known to be infected with COVID-19 shall be provided written, verbal, or electronic notification to observe the COVID-19 guidance for funeral home workers published by the United States Centers for Disease Control and Prevention, which is hereby incorporated by reference, including any subsequent amendments or editions, and available free of charge at: https://www.cdc.gov/coronavirus/2019-ncov/community/funeral-faqs.html.

History Note: *Authority G.S. 130A-144; 130A-146;*
Temporary Rule Eff. February 1, 1988, for a period of 180 days to expire on July 29, 1988;
Eff. March 1, 1988;
Recodified from 15A NCAC 19A .0204 Eff. June 11, 1991;
Temporary Amendment Eff. November 1, 2003;
Amended Eff. April 1, 2004;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. January 9, 2018;
Emergency Amendment Eff. September 25, 2020.

10A NCAC 41A .0213 CONTROL MEASURES -- SARS

Guidelines and recommended actions for prevention of the spread of Severe Acute Respiratory Syndrome (SARS) published by the Centers for Disease Control and Prevention (CDC) shall be the required control measures for SARS and are incorporated by reference, including subsequent amendments and editions. Copies of CDC guidelines contained in the Morbidity and Mortality weekly reports may be purchased from the Superintendent of Documents, US Government Printing Office, Washington DC 20402 for a total cost of three dollars and fifty cents ($3.50) each.

History Note: *Authority G.S. 130A-144;*
Temporary Adoption Eff. May 16, 2003;
Eff. August 1, 2004;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. January 9, 2018.

10A NCAC 41A .0214 CONTROL MEASURES - HEPATITIS C

The following are the control measures for hepatitis C infection:

(1) Infected persons shall not:
  (a) share needles or syringes, any other drug-related equipment or paraphernalia, or personal items, such as razors, that may be contaminated with blood through previous use; or
  (b) donate or sell blood, plasma, platelets, or other blood products.
(2) Persons with acute hepatitis C infection shall:
  (a) if the date of initial infection is known, identify to the local health director all needle partners since the date of infection;
  (b) if the date of initial infection is unknown, identify persons who have been needle partners during the previous six months.
(3) The attending physician shall:
  (a) advise all patients known to be at high risk, including injection drug users, hemodialysis patients, patients who received blood transfusions or solid organ transplants before July 1992, patients who received clotting factor concentrates made before 1987, persons with HIV infection, and persons with known exposure to hepatitis C, that they should be tested for hepatitis C;
  (b) advise infected persons of the potential for transmission to others via blood or body fluids;
  (c) provide or recommend that the infected patient seek medical evaluation for the presence or development of chronic liver disease; and
  (d) recommend that persons with chronic hepatitis C receive hepatitis A and hepatitis B vaccines unless serological testing indicates that they are immune to these infections by virtue of past infection or vaccination.

(4) When a health care worker or other person has a needlestick, non-intact skin, or mucous membrane exposure to blood or body fluids that would pose a significant risk of hepatitis C transmission if the source were infected with the hepatitis C virus, the following apply:

(a) When the source is known, the attending physician or occupational health care provider responsible for the exposed person, if other than the attending physician of the person whose blood or body fluids is the source of the exposure, shall notify the attending physician of the source that an exposure has occurred. The attending physician of the source person shall discuss the exposure with the source and, unless the source is already known to be infected, shall test the source for hepatitis C virus infection with or without consent unless it reasonably appears that the test cannot be performed without endangering the safety of the source person or the person administering the test. If the source person cannot be tested, an existing specimen of his or her blood, if one exists, shall be tested. The attending physician of the source person shall notify the attending physician of the exposed person of the infection status of the source.

(b) The attending physician of the exposed person shall inform the exposed person about the infection status of the source and shall instruct the exposed person regarding the necessity for protecting confidentiality. If the source person is infected with hepatitis C virus or the source person's infection status is unknown, the attending physician of the exposed person shall advise the exposed person to seek testing for hepatitis C virus infection as soon as possible and again four to six months after the exposure. If the source person was hepatitis C virus infected, the attending physician shall inform the exposed person of the measures required in Sub-Items (1)(a) through (b) of this Rule.

(5) The Centers for Disease Control and Prevention (CDC) Nationally Notifiable Diseases and Conditions (NNDC) Current Case Definitions for Hepatitis C are hereby incorporated by reference, including subsequent amendments and editions. The CDC NNDC may be accessed from the internet at (http://www.cdc.gov/osels/ph_surveillance/nndss/phs/infdis.htm). This document is also available for inspection at the North Carolina Division of Public Health, 1902 Mail Service Center, Raleigh NC 27603.

History Note: *Authority G.S. 130A-135; 130A-144;*
Eff. April, 1, 2012;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. January 9, 2018.

SECTION .0300 - SPECIAL CONTROL MEASURES

10A NCAC 41A .0301 DEFINITIONS

The following definitions shall apply in the interpretation of 10A NCAC 41A .0302:

(1) "Turtle" means any reptile of the order Testudines.

(2) "Institution" means a school, college, university, research laboratory, or other facility having a bona fide research or teaching interest in turtles.

History Note: *Authority G.S. 130A-144;*
Eff. February 1, 1976;
Readopted Eff. December 5, 1977;
Amended Eff. May 1, 1992;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. January 9, 2018.

10A NCAC 41A .0302 SALE OF TURTLES RESTRICTED

(a) To prevent the spread of salmonellosis from pet turtles to humans, no turtle with a carapace length of less than four inches shall be sold, offered for sale, or bartered by any retail or wholesale establishments except as follows:

(1) the sale of turtles shall be allowed to institutions for scientific or educational purposes;

(2) the sale of turtles shall be allowed for food purposes; and

(3) wholesale establishments dealing in the sale of turtles shall be allowed to sell turtles to other wholesale or retail establishments outside of the State of North Carolina, subject to the applicable state and federal laws.

(b) For establishments selling turtles in accordance with Paragraph (a) of this Rule, the following information, or words having similar meaning, shall be posted at every display of turtles for retail sale, printed on the sales receipt issued by the seller at the time of the sale, or printed on an information sheet accompanying the sales receipt issued by the seller:

"CAUTION: Children under 5 years old and people with weak immune systems (such as chemotherapy patients or those with HIV/AIDS) should avoid contact with reptiles. These people can get very sick from a germ called Salmonella that reptiles carry. Reptiles include lizards, snakes, alligators, and turtles. Wash hands thoroughly after handling turtles or material that had contact with turtles. Do not allow water or any other substance that had contact with turtles to come in contact with food or areas where food is prepared. Do not bathe turtles or clean their tanks in your kitchen or bathroom and do not have close contact with turtles which could allow direct contamination of the mouth (e.g., kissing, etc.)."

(c) The seller shall keep a record of all purchases, losses, and other dispositions of turtles for at least one year.

History Note: *Authority G.S. 130A-144;*
Eff. February 1, 1976;
Readopted Eff. December 5, 1977;
Amended Eff. May 1, 2017; February 3, 1992;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. January 9, 2018.

10A NCAC 41A .0303 RECORDING THE SALES OF BIRDS

(a) A business engaged in the retail sale of birds shall maintain a record of each sale for at least six months after the sale. The record shall include the name and address of the purchaser of each bird. The record shall be made available to the Department upon the request of the Department.

(b) This Rule shall not apply to the sale of birds for hunting, scientific, educational, agricultural or food purposes.

History Note: *Authority G.S. 130A-144;*
Eff. June 1, 1990;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. January 9, 2018.

SECTION .0400 - IMMUNIZATION

10A NCAC 41A .0401 DOSAGE AND AGE REQUIREMENTS FOR IMMUNIZATION

(a) Every individual in North Carolina required to be immunized pursuant to G.S. 130A-152 through 130A-157 shall be immunized against the following diseases and have documentation of age-appropriate vaccination in accordance with the Advisory Committee on Immunization Practices (ACIP).

(1) Diphtheria, tetanus, and pertussis (whooping cough) - five doses: three doses by age seven months; and 2 booster doses, the first by age 19 months and the second on or after the fourth birthday and before entering school for the first time. However:
   (A) Individuals who receive the first booster dose of diphtheria/tetanus/pertussis vaccine on or after the fourth birthday are not required to have a second booster.
   (B) Individuals entering college or university for the first time on or after July 1, 2008 must have had three doses of tetanus/diphtheria toxoid; one of which must be tetanus/diphtheria/pertussis.
   (C) A booster dose of tetanus/diphtheria/pertussis vaccine is required for individuals who have not previously received it and are entering the seventh grade or by 12 years of age, whichever comes first.

(2) Poliomyelitis vaccine - four doses: two doses of trivalent type by age five months; a third dose trivalent type before age 19 months; and a booster dose of trivalent type on or after his or her fourth birthday and before entering school for the first time. However:
   (A) An individual attending school who has attained his or her 18th birthday is not required to receive a polio vaccine.

(B) The requirements for the booster dose on or after the fourth birthday do not apply to individuals who began school before July 1, 2015.

(C) Individuals who receive the third dose of poliomyelitis vaccine on or after the fourth birthday are not required to receive a fourth dose if the third dose is given at least six months after the second dose.

(3) Measles (rubeola) vaccine - two doses of live, attenuated vaccine administered at least 28 days apart: the first dose on or after age 12 months and before age 16 months; and a second dose before entering school for the first time. However:

(A) An individual who has been documented by serological testing to have a protective antibody titer against measles is not required to receive measles vaccine.

(B) An individual who has been diagnosed before January 1, 1994, by a physician (or designee such as a nurse practitioner or physician's assistant) as having measles (rubeola) disease is not required to receive measles vaccine.

(C) An individual born before 1957 is not required to receive measles vaccine except in measles outbreak situations.

(D) The requirement for a second dose of measles vaccine does not apply to individuals who enter school or in college or university for the first time before July 1, 1994.

(4) Rubella vaccine - one dose of live, attenuated vaccine on or after age 12 months and before age 16 months. However:

(A) An individual who has laboratory confirmation of rubella disease or who has been documented by serological testing to have a protective antibody titer against rubella is not required to receive rubella vaccine.

(B) An individual who has attained his or her fiftieth birthday is not required to receive rubella vaccine except in outbreak situations.

(C) An individual who entered a college or university after his or her thirtieth birthday and before February 1, 1989 is not required to meet the requirement for rubella vaccine except in outbreak situations.

(5) Mumps vaccine – two doses: the first dose of live, attenuated vaccine administered on or after age 12 months and before age 16 months; and a second dose before entering school, college or university for the first time. However:

(A) An individual who has laboratory confirmation of disease, or has been documented by serological testing to have a protective antibody titer against mumps is not required to receive the mumps vaccine.

(B) An individual born before 1957 is not required to receive the mumps vaccine.

(C) The requirements for the mumps vaccine do not apply to individuals who entered the first grade for the first time before July 1, 1987 or college or university before July 1, 1994.

(D) An individual entering school, college or university before July 1, 2008 is not required to receive a second dose of mumps vaccine.

(6) Haemophilus influenzae, b conjugate vaccine - three doses of HbOC or PRP-T or two doses of PRP-OMP before age 7 months and a booster dose of any type on or after age 12 months and by age 16 months. However:

(A) Individuals who receive the first dose of Haemophilus influenzae, b vaccine on or after 7 months of age and before 12 months of age are required to have two doses of HbOC, PRP-T or PRP-OMP and a booster dose on or after 12 months of age and by age 16 months.

(B) Individuals who receive the first dose of Haemophilus influenzae, b vaccine on or after 12 months of age and before 15 months of age are required to have only 2 doses of HbOC, PRP-T or PRP-OMP and a booster dose two months later.

(C) Individuals who receive the first dose of Haemophilus influenzae, b vaccine on or after 15 months of age are required to have only one dose of any of the Haemophilus influenzae b conjugate vaccines.

(D) No individual who has passed his or her fifth birthday is required to be vaccinated against Haemophilus influenzae, b.

(7) Hepatitis B vaccine – three doses: the first dose by age 3 months, a second dose before age 5 months and a third dose by age 19 months. However:

(A) The last dose of the hepatitis B vaccine series shall not be administered before 24 weeks of age.

(B) Individuals born before July 1, 1994 are not required to be vaccinated against hepatitis B.

(8) Varicella vaccine – two doses administered at least 28 days apart; one dose on or after age 12 months of age and before age 19 months; and a second dose before entering school for the first time. However:

(A) An individual who has laboratory confirmation of varicella disease immunity or has been documented by serological testing to have a protective antibody titer against varicella is not required to varicella vaccine.

(B) An individual who has documentation from a physician, nurse practitioner, or physician's assistant verifying history of varicella disease is not required to receive varicella vaccine. The documentation shall include the name of the individual with a history of varicella disease, the approximate date or age of infection, and a healthcare provider signature.

(C) An individual born before April 1, 2001 is not required to receive varicella vaccine.

(D) The requirement for the second dose of varicella vaccine shall not apply to individuals who enter Kindergarten or first grade for the first time before July 1, 2015.

(9) Pneumococcal conjugate vaccine – Four doses; 3 doses by age 7 months and a booster dose at 12 through 15 months of age. However:

(A) Individuals who receive the first dose of pneumococcal conjugate vaccine on or after 7 months of age and before 12 months of age are required to have 2 doses at least 4 weeks apart; and a booster dose at 12 through 15 months of age.

(B) Individuals who receive the first dose of pneumococcal conjugate vaccine on or after 12 months of age and before 24 months of age are required to have 2 doses at least 8 weeks apart to complete the series.

(C) Individuals who receive the first dose of pneumococcal conjugate vaccine on or after 24 months of age and before 5 years are required to have 1 dose to complete the series.

(D) No individual who has passed his or her fifth birthday shall be required to be vaccinated against pneumococcal disease.

(E) An individual born before July 1, 2015 shall not be required to receive pneumococcal conjugate vaccine.

(10) Meningococcal conjugate vaccine – two doses: one dose is required for individuals entering the seventh grade or by 12 years of age, whichever comes first, on or after July 1, 2015. A booster dose is required by 17 years of age or by entering the 12th grade. However:

(A) The first dose does not apply to individuals who entered seventh grade before July 1, 2015.

(B) The booster dose does not apply to individuals who entered the 12^{th} grade before August 1, 2020.

(C) If the first dose is administered on or after the 16^{th} birthday, a booster dose is not required.

(D) An individual born before January 1, 2003 shall not be required to receive a meningococcal conjugate vaccine.

(b) The healthcare provider shall administer immunizations in accordance with this Rule. However, if a healthcare provider administers vaccine up to and including the fourth day prior to the required minimum age, the individual dose is not required to be repeated. Doses administered more than four days prior to the requirements are considered invalid doses and shall be repeated.

(c) The State Health Director may suspend temporarily any portion of the requirements of this Rule due to emergency conditions, such as the unavailability of vaccine. The Department shall give notice in writing to all local health departments and other providers currently receiving vaccine from the Department when the suspension takes effect and when the suspension is lifted. When any vaccine series is disrupted by such a suspension, the next dose shall be administered within 90 days of the lifting of the suspension and the series resumed in accordance with intervals determined by the most recent recommendations of the Advisory Committee on Immunization Practices. These recommendations may be accessed free of charge at http://www.cdc.gov/vaccines/acip/.

History Note: *Authority G.S. 130A-152(c); 130A-155.1;*
Eff. February 1, 1976;
Amended Eff. July 1, 1977;

Readopted Eff. December 5, 1977;
Temporary Amendment Eff. February 1, 1988, for a period of 180 days to expire on July 29, 1988;
Amended Eff. October 1, 1995; October 1, 1994; January 1, 1994; January 4, 1993;
Temporary Amendment Eff. February 23, 2000; August 20, 1999; May 21, 1999;
Amended Eff. August 1, 2000;
Temporary Amendment Eff. May 17, 2002; April 1, 2002; February 18, 2002; August 1, 2001;
Amended Eff. July 1, 2015; January 1, 2008; November 1, 2005; January 1, 2005; April 1, 2003;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. January 9, 2018.

10A NCAC 41A .0402 APPROVED VACCINE PREPARATIONS

All vaccine preparations licensed for interstate use by the Bureau of Biologic Standards of the U.S. Food and Drug Administration are approved for use in fulfilling the requirements of 10 NCAC 07A .0401.

History Note: *Authority G.S. 130A-152(c);*
Eff. February 1, 1976;
Readopted Eff. December 5, 1977;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. January 9, 2018.

10A NCAC 41A .0403 NON-RELIGIOUS PERSONAL BELIEF NO EXEMPTION

Except as provided in G.S. 130A-156 and G.S. 130A-157, and 10A NCAC 41A .0404 and .0405, no child shall be exempt from the requirements of 10A NCAC 41 .0401; there is no exception to these requirements for the case of a personal belief or philosophy of a parent or guardian not founded upon a religious belief.

History Note: *Authority G.S. 130A-152(c);*
Eff. February 1, 1976;
Readopted Eff. December 5, 1977;
Amended Eff. October 1, 1984; July 1, 1979;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. January 9, 2018.

10A NCAC 41A .0404 MEDICAL EXEMPTIONS FROM IMMUNIZATION

(a) Certification of a medical exemption by a physician pursuant to G.S. 130A-156 shall be in writing and shall state the basis of the exemption, the specific vaccine or vaccines the individual should not receive, and the length of time the exemption will apply for the individual.

(b) Medical contraindications for which medical exemptions may be certified by a physician for immunizations are included in the most recent General Recommendations of the Advisory Committee on Immunization Practices, Public Health Services, U.S. Department of Health and Human Services, published in the Centers for Disease Control and Prevention publication, the Morbidity and Mortality Weekly Report, which is adopted by reference including subsequent amendments and additions. A copy is available for inspection in the Immunization Section at 1330 St. Mary's Street, Raleigh, North Carolina. Internet access is available by searching www.cdc.gov/nip.

History Note: *Authority G.S. 130A-152(c); 130A-156;*
Eff. July 1, 1979;
Temporary Amendment Eff. February 1, 1988, for a period of 180 days to expire on July 29, 1988;
Amended Eff. August 1, 2000; January 4, 1993; February 1, 1990; March 1, 1988;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. January 9, 2018.

10A NCAC 41A .0405 EXEMPTION FOR CLINICAL STUDIES

An individual enrolled in a clinical trial of the efficacy of a new vaccine preparation or dosage schedule shall be exempted from those requirements of 10A NCAC 41A .0401 and .0402 which conflict with the trial protocol. This exemption shall only apply to individuals who:

(1) participate in a clinical trial whose protocol is approved by the State Health Director, and
(2) fully participate in and complete the clinical trial.

History Note: *Authority G.S. 130A-152(c);*
Eff. October 1, 1983;
Temporary Amendment Eff. February 1, 1988, for a period of 180 days to expire on July 29, 1988;
Amended Eff. March 1, 1988;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. January 9, 2018.

10A NCAC 41A .0406 ACCESS TO IMMUNIZATION INFORMATION

(a) Physicians, local health departments and the Department shall, upon request and without consent release the immunization information specified in Paragraph (b) of this Rule to the following organizations:

(1) schools K-12, whether public, private or religious;
(2) licensed and registered childcare facilities as defined in G.S. 110-86(3) and G.S. 110-101;
(3) Head Start;
(4) colleges and universities, whether public, private or religious;
(5) Health Maintenance Organizations; and
(6) Other state and local health departments outside of North Carolina.

(b) The following is the immunization information to be released to the organizations specified in Paragraph (a) of this Rule:

(1) name and address;
(2) name of the parent, guardian, or person standing in loco parentis;
(3) date of birth;
(4) gender;
(5) race and ethnicity;
(6) vaccine type, date and dose number administered;
(7) the name and address of the physician or local health department that administered each dose; and
(8) the existence of a medical or religious exemption determined by the Immunization Section to meet the requirements of G.S. 130A-156 and 10A NCAC 41A .0404 or G.S. 130A-157. If such a determination has not been made by the Division of Public Health, the person shall have access to the certification of medical and religious exemptions required by G.S. 130A-156 or G.S. 130A-157 and 10A NCAC 41A .0404.

History Note: *Authority G.S. 130A-153;*
Temporary Adoption Eff. August 9, 1993, for a period of 180 days or until the permanent rule becomes effective, whichever is sooner;
Eff. January 4, 1994;
Amended Eff. April 1, 2001; August 1, 2000; October 1, 1995;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. January 9, 2018.

SECTION .0500 - PURCHASE AND DISTRIBUTION OF VACCINE

10A NCAC 41A .0501 PURCHASE OF VACCINE

The Division of Public Health may enter into contracts for the purchase of vaccines. Any purchase of such vaccines shall be in accordance with Article 3 of G.S. 143 and 01 NCAC 05A.

History Note: *Authority S.L. 1986, c. 1008, s. 2;*
Temporary Rule Eff. October 5, 1986 for a period of 120 days to expire on February 1, 1987;
Eff. February 1, 1987;
Amended Eff. September 1, 1991;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. January 9, 2018.

10A NCAC 41A .0502 VACCINE FOR PROVIDERS OTHER THAN LOCAL HEALTH DEPARTMENTS

History Note: *Authority G.S. 130A-433;*
Temporary Rule Eff. October 5, 1986 for a period of 120 days to expire on February 1, 1987;
Temporary Rule Eff. February 1, 1987 for a period of 120 days to expire on May 31, 1987;
Eff. March 1, 1987;
Temporary Amendment Eff. February 1, 1988, for a period of 180 days to expire on July 29, 1988;
Temporary Amendment Eff. August 26, 1992, for a period 180 days or until the permanent rule becomes effective, whichever is sooner;
Temporary Amendment Eff. October 1, 1994, for a period of 180 days or until the permanent rule becomes effective, whichever is sooner;
Amended Eff. October 1, 1995; January 1, 1995; January 4, 1994; January 4, 1993;
Temporary Amendment Eff. December 1, 1998;
Amended Eff. August 1, 2000;
Temporary Amendment Eff. December 1, 2007;
Amended Eff. November 1, 2008;
Repealed Eff. July 1, 2014.

SECTION .0600 - SPECIAL PROGRAM/PROJECT FUNDING

10A NCAC 41A .0601 RESERVED FOR FUTURE CODIFICATION

10A NCAC 41A .0602 PROVIDER ELIGIBILITY
10A NCAC 41A .0603 APPLICATION FOR FUNDS
10A NCAC 41A .0604 REPORTS
10A NCAC 41A .0605 USE OF SPECIAL PROJECT FUNDS

History Note: *Authority G.S. 130A-5(3);*
Eff. June 1, 1988;
Amended Eff. September 1, 1990;
Expired Eff. February 1, 2018 pursuant to G.S. 150B-21.3A.

SECTION .0700 - LICENSED NURSING HOME SERVICES

10A NCAC 41A .0701 MEDICAL ELIGIBILITY FOR LICENSED NURSING HOME SERVICES

History Note: *Authority G.S. 130A-177;*
Eff. October 1, 1985;
Amended Eff. September 1, 1990;
Expired Eff. February 1, 2018 pursuant to G.S. 150B-21.3A.

SECTION .0800 - COMMUNICABLE DISEASE GRANTS AND CONTRACTS

10A NCAC 41A .0801 COMMUNICABLE DISEASE FINANCIAL GRANTS AND CONTRACTS

(a) The Division of Public Health may enter into financial arrangements with local health departments, community hospitals, nursing homes, or other convalescent facilities, and with physicians for the purpose of providing specific health care services for communicable diseases and the implementation of control measures.

(b) The Division of Public Health may authorize a local health department to obtain required diagnostic and treatment services for persons with syphilis, gonorrhea, chancroid, lymphogranuloma venereum, and granuloma inguinale from physicians:

(1) The amount to be charged for these services shall be negotiated between the local health department and the physician and approved by the Division of Public Health at the lowest agreeable rate, not to exceed approved Medicaid reimbursement rates. Drugs used in treatment may be provided to such physicians by the local health department.

(2) The physician shall bill the local health department for services provided. The local health department shall submit requests for payment to the Division of Public Health on forms provided by the Division of Public Health.

History Note: *Authority G.S. 130A-5; 130A-135; 130A-144;*
Eff. December 1, 1991;
Amended Eff. April 1, 2003;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. January 9, 2018.

10A NCAC 41A .0802 RESERVED FOR FUTURE CODIFICATION

10A NCAC 41A .0803 RESERVED FOR FUTURE CODIFICATION

SECTION .0900 - BIOLOGICAL AGENT REGISTRY

10A NCAC 41A .0901 GENERAL
The biological agent registry established by G.S. 130A-149 is administered by the Division of Public Health, 1915 Mail Service Center, Raleigh, North Carolina 27699-1915.

History Note: *Authority G.S. 130A-149;*
Temporary Adoption Eff. January 10, 2002;
Eff. April 1, 2003;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. January 9, 2018.

10A NCAC 41A .0902 BIOLOGICAL AGENTS TO BE REPORTED
The biological agents that shall be reported to the registry shall be those agents listed as select agents in 42 C.F.R. Part 72, Appendix A which is adopted herein by reference including subsequent amendments and editions. Copies of this federal provision may be inspected at and copies obtained from the Division of Public Health, 1915 Mail Service Center, Raleigh, North Carolina 27699-1915 at a cost of ten cents ($.10) per page at the time of adoption of this Rule.

History Note: *Authority G.S. 130A-149;*
Temporary Adoption Eff. January 10, 2002;
Eff. April 1, 2003;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. January 9, 2018.

10A NCAC 41A .0903 WHEN TO REPORT
A person possessing and maintaining a listed biological agent on the effective date of these Rules shall make a report within 45 days of the effective date of these Rules. A person who does not possess and maintain any listed biological agents on the effective date of these Rules shall make a report within seven days of receipt of such agents. A person shall make an amended report within seven days of any change in the information contained in the report. A person shall make a report within 24 hours of any suspected release, loss or theft of any listed biological agent.

History Note: *Authority G.S. 130A-149;*
Temporary Adoption Eff. January 10, 2002;
Eff. April 1, 2003;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. January 9, 2018.

10A NCAC 41A .0904 WHAT TO REPORT
The report shall be made on a form created by the Department and shall identify the listed biological agents possessed and maintained at the facility; shall specify the use of the agents for vaccine production, research purposes, quality control or other use; shall indicate the form of the agents; shall identify the physical location of the laboratories and the storage areas; and shall identify the person in charge of the agents.

History Note: *Authority G.S. 130A-149;*
Temporary Adoption Eff. January 10, 2002;

Eff. April 1, 2003;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. January 9, 2018.

10A NCAC 41A .0905 EXEMPTION FROM REPORTING

A person who detects a listed biological agent in a clinical or environmental sample for the purpose of diagnosing disease, epidemiological surveillance, exposure assessment, reference, verification or proficiency testing, and who discards the agent within 14 calendar days of receiving notice of the completion of confirmation testing, or discards the agent within 14 calendar days of using the agent for reference, verification or proficiency testing, is not required to make a report.

History Note: *Authority G.S. 130A-149;*
Temporary Adoption Eff. January 10, 2002;
Eff. April 1, 2003;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. January 9, 2018.

10A NCAC 41A .0906 SECURITY

All persons possessing and maintaining a listed biological agent must demonstrate compliance with all safeguards contained in the 42 C.F.R. Part 72 and the Rules promulgated thereunder, and must employ those federal safeguards over the agents they possess and maintain, regardless of whether the mere possession of the agent is itself required to be registered under federal law. The safeguards contained in 42 C.F.R. Part 72 and the Rules promulgated thereunder are adopted herein by reference including subsequent amendments and additions. Copies of this federal provision may be inspected at and copies obtained from the Division of Public Health, 1915 Mail Service Center, Raleigh, North Carolina 27699-1915, at a cost of ten cents ($.10) per page at the time of adoption of this Rule.

History Note: *Authority G.S. 130A-149;*
Temporary Adoption Eff. January 10, 2002;
Eff. April 1, 2003;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. January 9, 2018.

10A NCAC 41A .0907 RELEASE OF INFORMATION

The Department shall release information contained in the Biological Agents Registry only by order of the State Health Director upon a finding that the release is necessary for the conduct of a communicable disease investigation or for the investigation of a release, theft or loss of a biological agent.

History Note: *Authority G.S. 130A-149;*
Temporary Adoption Eff. January 10, 2002;
Eff. April 1, 2003;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. January 9, 2018.