CHAPTER 41 – HEALTH: EPIDEMIOLOGY

SUBCHAPTER 41A – COMMUNICABLE DISEASE CONTROL

SECTION .0100 – REPORTING OF COMMUNICABLE DISEASES

10A NCAC 41A .0101 REPORTABLE DISEASES AND CONDITIONS

(a) The following named diseases and conditions are declared to be dangerous to the public health and are hereby made reportable within the time period specified after the disease or condition is reasonably suspected to exist:

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

(46) pelvic inflammatory disease – 7 days;
(47) psittacosis - 7 days;
(48) Q fever - 7 days;
(49) rabies, human - 24 hours;
(50) Rocky Mountain spotted fever - 7 days;
(51) rubella - 24 hours;
(52) rubella congenital syndrome - 7 days;
(53) salmonellosis - 24 hours;
(54) severe acute respiratory syndrome (SARS) – 24 hours;
(55) shigellosis - 24 hours;
(56) smallpox –immediately;
(57) Staphylococcus aureus with reduced susceptibility to vancomycin – 24 hours;
(58) streptococcal infection, Group A, invasive disease - 7 days;
(59) syphilis - 24 hours;
(60) tetanus - 7 days;
(61) toxic shock syndrome - 7 days;
(62) trichinosis - 7 days;
(63) tuberculosis - 24 hours;
(64) tularemia - immediately;
(65) typhoid - 24 hours;
(66) typhoid carriage (Salmonella typhi) - 7 days;
(67) typhus, epidemic (louse-borne) - 7 days;
(68) vaccinia – 24 hours;
(69) vibrio infection (other than cholera) - 24 hours;
(70) whooping cough - 24 hours;
(71) yellow fever - 7 days.

(b) For purposes of reporting confirmed human immunodeficiency virus (HIV) infection is defined as a positive virus culture, repeatedly reactive EIA antibody test confirmed by western blot or indirect immunofluorescent antibody test, positive nucleic acid detection (NAT) test, or other confirmed testing method approved by the Director of the State Public Health Laboratory conducted on or after February 1, 1990. In selecting additional tests for approval, the Director of the State Public Health Laboratory shall consider whether such tests have been approved by the federal Food and Drug Administration, recommended by the federal Centers for Disease Control and Prevention, and endorsed by the Association of Public Health Laboratories.

(c) In addition to the laboratory reports for Mycobacterium tuberculosis, Neisseria gonorrhoeae, and syphilis specified in G.S. 130A-139, laboratories shall report:

(1) Isolation or other specific identification of the following organisms or their products from human clinical specimens:
  (A) Any hantavirus or hemorrhagic fever virus.
  (B) Arthropod-borne virus (any type).
  (C) Bacillus anthracis, the cause of anthrax.
  (D) Bordetella pertussis, the cause of whooping cough (pertussis).
  (E) Borrelia burgdorferi, the cause of Lyme disease (confirmed tests).
  (F) Brucella spp., the causes of brucellosis.
  (G) Campylobacter spp., the causes of campylobacteriosis.
  (H) Chlamydia trachomatis, the cause of genital chlamydial infection, conjunctivitis (adult and newborn) and pneumonia of newborns.
  (I) Clostridium botulinum, a cause of botulism.
  (J) Clostridium tetani, the cause of tetanus.
  (K) Corynebacterium diphtheriae, the cause of diphtheria.
  (L) Coxiella burnetii, the cause of Q fever.
  (M) Cryptosporidium parvum, the cause of human cryptosporidiosis.
  (N) Cyclospora cayetanesis, the cause of cyclosporiasis.
  (O) Ehrlichia spp., the causes of ehrlichiosis.
  (P) Shiga toxin-producing Escherichia coli, a cause of hemorrhagic colitis, hemolytic uremic syndrome, and thrombotic thrombocytopenic purpura.

(Q) Francisella tularensis, the cause of tularemia.
(R) Hepatitis B virus or any component thereof, such as hepatitis B surface antigen.
(S) Human Immunodeficiency Virus, the cause of AIDS.
(T) Legionella spp., the causes of legionellosis.
(U) Leptospira spp., the causes of leptospirosis.
(V) Listeria monocytogenes, the cause of listeriosis.
(W) Monkeypox.
(X) Mycobacterium leprae, the cause of leprosy.
(Y) Plasmodium falciparum, P. malariae, P. ovale, and P. vivax, the causes of malaria in humans.
(Z) Poliovirus (any), the cause of poliomyelitis.
(AA) Rabies virus.
(BB) Rickettsia rickettsii, the cause of Rocky Mountain spotted fever.
(CC) Rubella virus.
(DD) Salmonella spp., the causes of salmonellosis.
(EE) Shigella spp., the causes of shigellosis.
(FF) Smallpox virus, the cause of smallpox.
(GG) Staphylococcus aureus with reduced susceptibility to vanomycin.
(HH) Trichinella spiralis, the cause of trichinosis.
(II) Vaccinia virus.
(JJ) Vibrio spp., the causes of cholera and other vibrioses.
(KK) Yellow fever virus.
(LL) Yersinia pestis, the cause of plague.

(2) Isolation or other specific identification of the following organisms from normally sterile human body sites:
(A) Group A Streptococcus pyogenes (group A streptococci).
(B) Haemophilus influenzae, serotype b.
(C) Neisseria meningitidis, the cause of meningococcal disease.

(3) Positive serologic test results, as specified, for the following infections:
(A) Fourfold or greater changes or equivalent changes in serum antibody titers to:
(i) Any arthropod-borne viruses associated with meningitis or encephalitis in a human.
(ii) Any hantavirus or hemorrhagic fever virus.
(iii) Chlamydia psittaci, the cause of psittacosis.
(iv) Coxiella burnetii, the cause of Q fever.
(v) Dengue virus.
(vi) Ehrlichia spp., the causes of ehrlichiosis.
(vii) Measles (rubeola) virus.
(viii) Mumps virus.
(ix) Rickettsia rickettsii, the cause of Rocky Mountain spotted fever.
(x) Rubella virus.
(xi) Yellow fever virus.
(B) The presence of IgM serum antibodies to:
(i) Chlamydia psittaci
(ii) Hepatitis A virus.
(iii) Hepatitis B virus core antigen.
(iv) Rubella virus.
(v) Rubeola (measles) virus.
(vi) Yellow fever virus.

(4) Laboratory results from tests to determine the absolute and relative counts for the T-helper (CD4) subset of lymphocytes that have a level below that specified by the Centers for Disease Control and Prevention as the criteria used to define an AIDS diagnosis.

History Note: *Authority G.S. 130A-134; 130A-135; 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 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, 2010.

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.

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.

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: *Temporary Rule Eff. February 1, 1988, for a period of 180 days to expire on July 29, 1988;*
Authority G.S. 130A-143(9);
Eff. March 1, 1988;
Amended Eff. September 1, 1991.

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.

CHAPTER 41 – HEALTH: EPIDEMIOLOGY

SUBCHAPTER 41A – COMMUNICABLE DISEASE CONTROL

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.

10A NCAC 41A .0202 CONTROL MEASURES – HIV

The following are the control measures for the Acquired Immune Deficiency Syndrome (AIDS) and Human Immunodeficiency Virus (HIV) infection:

(1) Infected persons shall:
  (a) refrain from sexual intercourse unless condoms are used; exercise caution when using condoms due to possible condom failure;
  (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;
  (d) have a skin test for tuberculosis;
  (e) notify future sexual intercourse partners of the infection;
  (f) if the time of initial infection is known, notify persons who have been sexual intercourse and needle partners since the date of infection; and,
  (g) if the date of initial infection is unknown, notify persons who have been sexual intercourse and needle partners for the previous year.
(2) The attending physician shall:
  (a) give the control measures in Item (1) of this Rule to infected patients, in accordance with 10A NCAC 41A .0210;
  (b) If the attending physician knows the identity of the spouse of an HIV-infected patient and has not, with the consent of the infected patient, notified and counseled the spouse, the physician shall list the spouse on a form provided by the Division of Public Health and shall mail the form to the Division. The Division shall undertake to counsel the spouse. The attending physician's responsibility to notify exposed and potentially exposed persons is satisfied by fulfilling the requirements of Sub-Items (2)(a) and (b) of this Rule;
  (c) advise infected persons concerning clean-up of blood and other body fluids;
  (d) advise infected persons concerning the risk of perinatal transmission and transmission by breastfeeding.
(3) The attending physician of a child who is infected with HIV 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 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 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.

(i) 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.

(ii) 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.

(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;

(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 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 infected with HIV, 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 infected, shall test the source for HIV infection 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, if one exists, shall be tested. The attending physician of the exposed person shall be notified 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 up to one year to determine whether transmission occurred, and, if the source person was HIV infected, give the exposed person the control measures listed in Sub-Items (1)(a) through (c) of this Rule. The attending physician of the exposed person shall instruct the exposed person regarding the necessity for protecting confidentiality.

(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 up to one year to determine whether transmission occurred.

(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, in good faith, has reasonable cause to suspect a patient infected 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, in good faith, has reasonable cause to suspect a person infected 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 mentally retarded, the local health director shall confer with the attending mental health physician or mental health authority 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 Correction and the prison facility administrator when any person confined in a state prison is determined to be infected with HIV. If the prison facility administrator, in consultation with the Director of Health Services, determines that a confined HIV infected person 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 payors 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 infected with HIV is required, must be individualized, and shall include referrals for medical and psychosocial services and control measures.

(11) A local health department or the Department may release information regarding an infected person pursuant to G.S. 130A-143(3) only when the local health department or the Department has provided direct medical care to the infected person and refers the person to or consults with the health care provider to whom the information is released.

(12) 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 and may include one or more of the following available and appropriate services:

(a) substance abuse counseling and treatment;

(b) mental health counseling and treatment; and

(c) education and counseling sessions about HIV, HIV transmission, and behavior change required to prevent transmission.

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

(14) 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 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. However, labor and delivery providers who do not currently have the capacity to perform rapid HIV testing are not required to use a rapid HIV test until January 1, 2009.

(15) 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. However, providers who do not currently have the capacity to perform rapid HIV testing shall not be required to use a rapid HIV test until January 1, 2009.

(16) Testing for HIV may be offered as part of routine laboratory testing panels using a general consent which 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. November 1, 2007; April 1, 2005; April 1, 2003.

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.

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 t h e 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.

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 the provisions of the Control of Communicable Diseases Manual which is hereby incorporated by reference including subsequent amendments and editions. Copies of this publication may be purchased from the American Public Health Association, Publication Sales Department, Post Office Box 753, Waldorf, MD 20604 for a cost of twenty-two dollars ($22.00) each plus five dollars ($5.00) shipping and handling. A copy is available for inspection in the Division of Public Health, 1931 Mail Service Center, Raleigh, North Carolina 27699-1931.

(b) The following persons shall be skin tested for tuberculosis and given appropriate clinical, microbiologic and x-ray examination in accordance with the "Diagnostic Standards and Classification of Tuberculosis in Adults and Children," published by the American Thoracic Society. The recommendations contained in this reference shall be the required control measures for evaluation, testing, and diagnosis for tuberculosis patients, contacts and suspects, except as otherwise provided in this Rule and are incorporated by reference including subsequent amendments and editions:

(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 which are incorporated by reference in Rule .0201 of this Section. If the contact's initial skin test is negative (0-4mm), and the case is confirmed by culture, a repeat skin 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, and staff with direct inmate contact in, the Department of Corrections upon incarceration or employment, and annually thereafter;

(4) Patients and staff in long term care facilities upon admission or employment. The two-step skin test method shall be used if the individual has not had a documented tuberculin skin test within the preceding 12 months;

(5) Staff in adult day care centers providing care for persons with HIV infection or AIDS upon employment. The two-step skin test method shall be used if the individual has not had a documented tuberculin skin test within the preceding 12 months; and

(6) Persons with HIV infection or AIDS.

A copy of "Diagnostic Standards and Classification of Tuberculosis in Adults and Children" 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/nchstp/tb/pubs/mmwrhtml/Maj_guide/cdc_ats_guidelines.htm.

(c) Treatment and follow-up for tuberculosis infection or disease shall be in accordance with "Treatment of Tuberculosis," published by the American Thoracic Society. The recommendations contained in this reference shall be the required control measures for testing, treatment, and follow-up for tuberculosis patients, contacts and suspects, except as otherwise provided in this Rule and are incorporated by reference including subsequent amendments and editions. Copies of this publication are 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/nchstp/tb/pubs/mmwrhtml/Maj_guide/cdc_ats_guidelines.htm.

(d) The attending physician or designee shall instruct all patients treated for tuberculosis regarding the potential side effects of the medications prescribed and prescribed medications, including instructions to promptly notify the physician or designee if side effects occur.

(e) Persons with active tuberculosis disease shall complete a standard multi-drug regimen, unless otherwise approved by the State Tuberculosis Medical Director or designee, and shall be managed using Directly Observed Therapy (DOT), which is the actual observation of medication ingestion by a health care worker (HCW).

(f) Persons with suspected or known active pulmonary or laryngeal tuberculosis who have sputum smears positive for acid fast bacilli are 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, including respiratory isolation or isolation in their home, may be discontinued when:

(1) They have three consecutive sputum smears collected at least eight hours apart which are negative; and

(2) They have been compliant on tuberculosis medications to which the organism is judged to be susceptible and there is evidence of clinical response to tuberculosis treatment.

(g) Persons with suspected or known active pulmonary or laryngeal tuberculosis who are initially sputum smear negative do not require respiratory isolation once they have been started on tuberculosis 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.

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.

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.

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.

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.

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: *Filed as a Temporary Rule Eff. February 1, 1988, for a period of 180 days to expire on July 29, 1988;*
Authority G.S. 130A-144;
Eff. March 1, 1988;
Recodified from 15A NCAC 19A .0202 Eff. June 11, 1991.

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: *Filed as a Temporary Rule Eff. February 1, 1988, for a period of 180 days to expire on July 29, 1988;*
Authority G.S. 130A-143; 130A-144;
Eff. March 1, 1988;
Amended Eff. June 1, 1989;
Recodified from 15A NCAC 19A .0203 Eff. June 11, 1991.

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

(a) It shall be the duty of the physician attending any person who dies and is known to be infected with HIV, plague, or hepatitis B 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 notification to all individuals handling the body of the proper precautions to prevent infection. This written notification shall be provided to funeral service personnel 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 attending physician shall notify the funeral service personnel verbally of the precautions required as soon as the physician becomes aware of the death. These precautions are noted in Paragraphs (b) and (c).

(b) 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.
(c) 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 notification to observe blood and body fluid precautions.

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.

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.

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.

10A NCAC 41A .0302 SALE OF TURTLES RESTRICTED
(a) Purpose of this Regulation. This Regulation is adopted to prevent the spread of salmonellosis from pet turtles to humans.
(b) Sale of Turtles Prohibited. No turtle shall be sold, offered for sale, or bartered by any retail or wholesale establishment in North Carolina.
(c) Sale of Turtles for Scientific, Educational, or Food Purposes Exempted. Subsection (b) of this Regulation does not apply to the sale of turtles to institutions for scientific or educational purposes nor to the sale of turtles for food purposes.
(d) Sale of Turtles Outside North Carolina Exempted. Notwithstanding the provisions of Subsection (b) of this Regulation, wholesale establishments in North Carolina dealing in the sale of turtles shall not be prohibited from selling turtles to other wholesale or retail establishments outside the State of North Carolina.
(e) Determination of Compliance. Authorized agents of the Department of Environment, Health, and Natural Resources and local health departments shall have authority to enter any retail or wholesale establishment at all times to determine compliance with this Regulation.

History Note: *Authority G.S. 130A-144;*
Eff. February 1, 1976;
Readopted Eff. December 5, 1977;
Amended Eff. February 3, 1992.

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.

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 by receiving the specified minimum doses of vaccines by the specified ages:

(1) Diphtheria, tetanus, and whooping cough vaccine -- five doses: three doses by age seven months and two booster doses, one by age 19 months and the second on or after the fourth birthday and before enrolling in school for the first time. However:
   (A) Individuals who receive the first booster dose of diphtheria, tetanus, and whooping cough vaccine on or after the fourth birthday are not required to have a second booster dose;
   (B) Individuals attending colleges and universities are required to have three doses of tetanus/diphtheria toxoid, one of which must have been within the last 10 years. Those individuals enrolling in college or university for the first time on or after July 1, 2008 must have had three doses of tetanus/diphtheria toxoid and a booster dose of tetanus/diphtheria/pertussis vaccine if a tetanus/diphtheria toxoid or tetanus/diphtheria/pertussis vaccine has not been administered within the past 10 years. A dose of tetanus/diphtheria/pertussis vaccine is not required for any student over the age of 64 years;
   (C) A booster dose of tetanus/diphtheria/pertussis vaccine is required for individuals attending public school who are entering the sixth grade on or after August 1, 2008, if five years or more have passed since the last dose of tetanus/diphtheria toxoid. A booster dose of tetanus/diphtheria/pertussis vaccine is required for individuals not attending public schools who are 12 years of age on or after August 1, 2008, if five years or more have passed since the last dose of tetanus/diphtheria toxoid. However, pertussis (whooping cough) vaccine is not required for individuals between 7 years of age through the fifth grade for those attending public schools and 7 through 12 years of age for those not attending public schools.

(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 before enrolling in school for the first time. However:
   (A) An individual attending school who has attained his or her 18th birthday is not required to receive polio vaccine;
   (B) Individuals who receive the third dose of poliomyelitis vaccine on or after the fourth birthday are not required to receive a fourth dose;
   (C) The requirements for booster doses of poliomyelitis vaccine do not apply to individuals who enrolled for the first time in the first grade before July 1, 1987.

(3) Measles (rubeola) vaccine--two doses of live, attenuated vaccine administered at least 28 days apart: one dose on or after age 12 months and before age 16 months and a second dose before enrolling in 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 prior to January 1, 1994, by a physician licensed to practice medicine as having measles (rubeola) disease is not required to receive measles vaccine;
   (C) An individual born prior to 1957 is not required to receive measles vaccine;
   (D) The requirement for a second dose of measles vaccine does not apply to individuals who enroll in 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 been documented by serologic 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--one dose of live, attenuated vaccine administered on or after age 12 months and before age 16 months and a second dose before enrolling in school, college or university for the first time. However:
  (A) An individual born prior to 1957 is not required to receive mumps vaccine;
  (B) The requirements for mumps vaccine do not apply to individuals who enrolled for the first time in the first grade before July 1, 1987 or in college or university before July 1, 1994;
  (C) An individual who has been documented by serological testing to have a protective antibody titer against mumps is not required to receive mumps vaccine;
  (D) An individual entering school, college or university prior to 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 seven months and a booster dose of any type on or after age 12 months and by age 16 months. However:
  (A) Individuals born before October 1, 1988 are not required to be vaccinated against *Haemophilus influenzae, b;*
  (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 two doses of HbOC, PRP-T or PRP-OMP;
  (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* conjugate vaccines, including PRP-D;
  (D) No individual who has passed their fifth birthday is required to be vaccinated against *Haemophilus influenzae, b.*

(7) Hepatitis B vaccine--three doses: one dose by age three months, a second dose before age five months and a third dose by age 19 months. However:
  (A) The last dose of the hepatitis B vaccine series shall not be administered prior to 24 weeks of age;
  (B) Individuals born before July 1, 1994 are not required to be vaccinated against hepatitis B.

(8) Varicella vaccine--1 dose administered on or after age 12 months and before age 19 months. However:
  (A) An individual with a laboratory test indicating immunity or with a history of varicella disease, documented by a health care provider, parent, guardian or person in loco parentis is not required to receive varicella vaccine. Serologic proof of immunity or documentation of previous illness must be presented whenever a certificate of immunization is required by North Carolina General Statute. The documentation shall include the name of the individual with a history of varicella disease and the approximate date or age of infection. Previous illness shall be documented by:
    (i) a written statement from a health care provider documented on or attached to the lifetime immunization card or certificate of immunization; or
    (ii) a written statement from the individual's parent, guardian or person in loco parentis attached to the lifetime immunization card or certificate of immunization.
  (B) An individual born prior to April 1, 2001 is not required to receive varicella 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 4 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.

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. January 1, 2008; November 1, 2005; January 1, 2005; April 1, 2003.

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.

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.

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: *Filed as a Temporary Amendment Eff. February 1, 1988, for a period of 180 days to expire on July 29, 1988;*
Authority G.S. 130A-152(c); 130A-156;
Eff. July 1, 1979;
Amended Eff. August 1, 2000; January 4, 1993; February 1, 1990; March 1, 1988.

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: *Filed as a Temporary Amendment Eff. February 1, 1988, for a period of 180 days to expire on July 29, 1988;*
Authority G.S. 130A-152(c);
Eff. October 1, 1983;
Amended Eff. March 1, 1988.

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.

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: *Temporary Rule Eff. October 5, 1986 for a period of 120 days to expire on February 1, 1987;*
Authority S.L. 1986, c. 1008, s. 2;
Eff. February 1, 1987;
Amended Eff. September 1, 1991.

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

(a) The Division of Public Health shall provide vaccines required by law free of charge to the following providers for administration to individuals who need vaccines to meet the requirement of G.S. 130A-152, 130-155.1 and 10A NCAC 41A .0401:

(1) Community, migrant, and rural health centers;
(2) Colleges and universities for students; and
(3) Physicians and other health care providers.

(b) Upon request of the Division, required vaccines may be distributed by local health departments operating as agents of the State to providers listed in Subparagraphs (a)(1), (2) and (3) of this Rule.

(c) Providers authorized in Paragraph (a) of this Rule shall receive free vaccines from the Division only if they sign an agreement with the Division. This agreement shall be prepared by the Division of Public Health and shall require the provider to:

(1) Charge vaccine administration fees at no more than the rates established by the State's Medicaid program. The State's Medicaid rates may be inspected at the Division of Public Health. Copies may also be obtained from the Division of Public Health at no charge;
(2) Provide all vaccines needed during a visit unless a specific contraindication exists to one or more of the vaccine;
(3) Charge no office fee in addition to an administration fee for an immunization-only visit;
(4) Agree not to charge an administration fee to an individual who states that he/she is unable to pay;
(5) Impose no condition as a prerequisite to receiving vaccine;
(6) Submit a monthly doses administered report by the tenth of each month electronically through the North Carolina Immunization Registry or on a form provided by the Immunization Section;
(7) Report adverse vaccine reactions through the Vaccine Adverse Event Reporting System (VAERS);
(8) Provide the latest edition of the applicable Important Information Statement (IIS), or Vaccine Information Statement (VIS) to the parent, guardian, or person standing in loco parentis for each dose of vaccine administered; document this action within the patient's permanent medical record; retain the documentation for a period of 10 years following the end of the calendar year in which the vaccine dose was administered, or for 10 years following the recipient's age of majority, whichever is longer; upon request, furnish copies of the documentation to the local health department or the Division; and keep a record of the vaccine manufacturer, lot number, and date of administration for each dose of vaccine administered;
(9) Allow periodic inspection of their vaccine supplies and records by the Division of Public Health; and
(10) Comply with the rules of this Section.

(d) A provider who fails to submit timely and accurate reports as required each month shall have vaccine shipments withheld until that month's report is received by the Immunization Section.

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.

SECTION .0600 - SPECIAL PROGRAM/PROJECT FUNDING

10A NCAC 41A .0601 RESERVED FOR FUTURE CODIFICATION

10A NCAC 41A .0602 PROVIDER ELIGIBILITY

The following organizations are eligible to apply for special project funds from the Division of Public Health:

(1) local health departments; and

(2) Non-profit or governmental groups such as public health, educational, and voluntary organizations.

History Note: *Authority G.S. 130A-5(3);*
Eff. June 1, 1988.

10A NCAC 41A .0603 APPLICATION FOR FUNDS

(a) Grants for special projects shall be awarded through a request for proposal (RFP) process that includes notification of all local health departments of the eligibility criteria, requirements for funding, and duration of the project period. This information shall also be available to other groups or organizations who may wish to apply. Requests for proposals may be obtained from the Division of Public Health, 1915 Mail Service Center, Raleigh, North Carolina 27699-1915.

(b) The grant proposal shall include the following:

(1) a project plan which includes an assessment of the need for the special project, measurable project objectives, and strategies for meeting the project objectives;

(2) a proposed budget; and

(3) an evaluation plan.

(c) In making the determination of which applications to approve for funding, each proposal will be judged on its own merits in competition with all the other proposals submitted to the Section. Proposals shall be judged according to the following criteria:

(1) the proposal demonstrates that a substantial need exists;

(2) the proposed project makes a significant contribution in meeting the established need; and

(3) the proposed project can be successfully completed within a reasonable period of time.

(d) The Division of Epidemiology shall review all grant proposals submitted on or before the deadline for submission of proposals. The Division of Public Health shall approve or deny a grant proposal within 60 days after the deadline for receipt of the grant proposal.

(e) A contract shall be signed with each applicant that is approved for funding. The number and type of services to be provided under the contract shall be negotiated with each contractor, approved by the Division of Public Health, and included as an addendum to the contract. Contracts may be renewed upon expiration of the contract period when the contractor's proposal meets the criteria in (c)(1) of this Rule, the contractor has demonstrated adequate performance, and funds are available.

History Note: *Authority G.S. 130A-5(3);*
Eff. June 1, 1988;
Amended Eff. September 1, 1990.

10A NCAC 41A .0604 REPORTS

(a) The contractor shall submit periodic performance reports as specified in the contract.

(b) The contractor shall submit a final report at the close of the contract period. The report shall include an evaluation addressing progress in meeting the objectives outlined in the application.

History Note: *Authority G.S. 130A-5(3);*
Eff. June 1, 1988.

10A NCAC 41A .0605 USE OF SPECIAL PROJECT FUNDS

(a) Special Project Funds provided pursuant to these Rules shall be expended solely for the purposes for which the funds were made available in accordance with the approved application, negotiated project objectives and budget, the rules in this Section, the terms and conditions of the award, and the applicable state costs principles.

(b) A contractor that consistently fails to meet acceptable levels of performance, as determined through site visits, review of performance reports, and other appropriate and generally accepted performance standards, and has been offered consultation and technical assistance, may have special project funds reduced or discontinued. Recommendations to reduce or discontinue funding shall be reviewed and approved by the State Health Director.

History Note: *Authority G.S. 130A-5(3);*
Eff. June 1, 1988.

SECTION .0700 - LICENSED NURSING HOME SERVICES

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

(a) A patient shall be medically eligible for reimbursement for up to 60 days per year, beginning the first day of financial eligibility, for treatment and convalescence services at a contract nursing home if the tuberculosis control branch finds that the following criteria are met:

(1) The applicant must have active pulmonary or disseminated tuberculosis associated with incapacitation or significant debilitation which requires a SNF or ICF level of care. To aid in making this determination, the referring physician shall provide a treatment plan and project a length of stay for the patient at the nursing home.

(2) The applicant must have positive bacteriology for tuberculosis. The positive bacteriology (AFB) must have been obtained within the preceding 14 days.

(3) The applicant must not be in need of an acute level of hospital care for any condition.

(4) The applicant must be 16 years of age or over.

(5) The applicant must be referred by a licensed physician who has first-hand knowledge of the applicant's mental and physical condition. The referring physician must furnish a summary of the applicant's physical and mental condition and known infirmities, and specific details of treatment and medication the applicant is taking with recommendations as to dosage, frequency and duration. This summary must include all known allergies as well as anti-tuberculosis and all other medications that the patient is taking. In addition, dietary needs, pertinent x-rays, and copies of laboratory reports must be forwarded, either with the patient, if accepted for admission, or in advance.

(6) The head of the Tuberculosis Control Branch may make exceptions to the criteria contained in (1) through (5) of this Paragraph upon a determination that a patient could be best treated for a tuberculosis condition at a licensed nursing home.

(b) If the head of the Tuberculosis Control Branch determines that additional treatment or convalescent care at a licensed nursing home is medically necessary because of the tuberculosis condition, the head of the Branch may extend medical eligibility for more than 60 days per year.

(c) The medical care payments described in this Rule are available only for services provided at a licensed nursing home which has contracted with the tuberculosis program for these services. Further payment limitations are found in 10A NCAC 45A .0300.

History Note: *Authority G.S. 130A-177;*
Eff. October 1, 1985;
Amended Eff. September 1, 1990.

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.

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.

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.

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.

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.

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.

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.

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.