HEALTH AND SENIOR SERVICES

PUBLIC HEALTH SERVICES BRANCH

DIVISION OF EPIDEMIOLOGY, ENVIRONMENTAL, AND OCCUPATIONAL HEALTH

COMMUNICABLE DISEASE SERVICE

Communicable Diseases

Proposed Readoption with Amendments: N.J.A.C. 8:57

Proposed Repeals: N.J.A.C. 8:57-2.1, 2.11, 5.3, 5.4, 5.5, 5.6, 5.8, 5.10, 5.11, 5.12, 5.15, and 5.16

Proposed New Rules: N.J.A.C. 8:57-1.2, 1.8, 1.15, 8:57-1 Appendices A and B, 2.1, 2.2, 2.3, 2.10, 8:57-2 Appendices A through G, 5.2, 5.4, 5.5, 5.6, 5.7, 5.8, 5.9, 5.10, 5.11, 5.12, 5.14, 8:57-5 Appendices A and B, 6.2, 6.3, 6.9, 8:57-6 Appendix, 8.2; and N.J.A.C. 8:58-1.1, 1.2, 1.3 and 8:58 Appendix

Proposed Amendments: N.J.A.C. 8:36-18.4, 8:39-27.4, 8:43D-15.4, 8:43H-20.2, and 8:52-12.3

Authorized By: _____, Fred M. Jacobs, M.D., J.D., Commissioner, Department of Health and Senior Services (in consultation with the Public Health Council, Herbert Yardley, M.A., Chair).

Authority: N.J.S.A. 26:1A-7; 26:1A-15; N.J.S.A. 26:2-137.1; 26:2H-12.35 et seq., 26:4-1 et seq., particularly 26:4-2 and 4-70; 26:5C-1 et seq., particularly 26:5C-6 and 5C-20; 17:23A-13; 18A:61D-1 et seq., particularly 18A:61D-6, 18A:62-15, 15.1 and 15.2; and 30:9-57.

Authority for N.J.A.C. 8:57-3 recodified as N.J.A.C. 8:58: N.J.S.A. 26:1A-7 and 1A-15.

Calendar Reference: See Summary below for explanation of exception to calendar requirement.

Proposal Number: PRN 2008- .

A public hearing on the proposed readoption with amendments, and proposed new rules, repeals, and amendments will be held at A.M. on , 2008 at the following address:

New Jersey Department of Health and Senior Services

First Floor Auditorium

Health and Agriculture Building

369 South Warren Streets (at Market Street)

Trenton, New Jersey 08608

(This address is provided to assist interested persons in obtaining driving directions by means of computerized mapping programs; do not mail comments to this address, as it is undeliverable.)

Persons wishing to comment on the proposal at the public hearing who wish to be placed on the list of speakers are requested to telephone at by , 2008, and to bring an extra written copy of their remarks for submission to the public record.

Other persons not attending the public hearing but wishing to submit written comments on the proposal should postmark and mail their comments on or before 2008 to:

Ruth Charbonneau, Director

Office of Legal and Regulatory Affairs

Office of the Commissioner

Department of Health and Senior Services

PO Box 360

Trenton, NJ 08625-0360

The agency proposal follows:

Summary

The Department of Health and Senior Services (Department) proposes the readoption with amendments of N.J.A.C. 8:57, Communicable Diseases. The Department also proposes repeals and new rules at N.J.A.C. 8:57. N.J.A.C. 8:57 is scheduled to expire on September 25, 2008, in accordance with N.J.S.A. 52:14B-5.1 and Executive Order No. 66 (1978). In accordance with N.J.S.A. 52:14B-5.1(c), the filing of this notice of proposal with the Office of Administrative Law prior to September 25, 2008, operates to extend the expiration date of N.J.A.C. 8:57 to March 24, 2009.

The Department proposes this readoption with amendments, repeals, and new rules in consultation with the New Jersey Public Health Council (PHC). Former Governor Codey's Reorganization Plan No.003-2005 (June 27, 2005), 37

N.J.R. 2735 (a) (August 1, 2005) recasted the role of the PHC, established at N.J.S.A. 26:1A-7, as being of a consultative and advisory nature in relation to the powers of the Commissioner of the Department of Health and Senior Services.

The Department has reviewed N.J.A.C. 8:57 and has determined that the existing rules continue to be necessary, adequate, reasonable, efficient, understandable and responsive to the purposes for which they were originally promulgated. The rules proposed for readoption with amendments would continue to provide the regulatory framework to fulfill the Department's obligation to protect public health through: monitoring, preventing and responding to communicable diseases; monitoring and improving service delivery for persons with HIV and AIDS; establishing required immunizations for entry into schools, child care centers, and institutions of higher education; and establishing the requirement for health insurance coverage for students attending an institution of higher education and for insurance carriers to provide benefits for childhood immunizations. The Department will discuss the proposed amendments, repeals, new rules and the resulting recodifications in this Summary under the appropriate subchapters. The Department has determined that it is appropriate to recodify N.J.A.C. 8:57-3 into its own chapter at N.J.A.C. 8:58 because occupational and environmental diseases, injuries, and poisonings are markedly different in scope, source, and preventability than communicable diseases and therefore warrant their own chapter. N.J.A.C. 8:57-3 proposed for recodification as N.J.A.C. 8:58 would continue to establish the regulatory

framework for the Department to conduct surveillance and research activities in order to prevent occupational and environmental diseases, injuries, and poisonings.

The Department proposes amendments at the following other sections N.J.A.C. 8:36-18.4, 8:39-27.4; 8:43D-15.4, 8:43H-20.2, and 8:52-12.3, which currently cite to existing sections of the rules at N.J.A.C. 8:57 that the Department has proposed for readoption with amendments and recodification in this rulemaking. The Department proposes amendments of those other chapters in this rulemaking to correct the existing citations in those other chapters to the particular sections of the rules at N.J.A.C. 8:57 that will be amended and recodified because of this rulemaking. The Department will discuss the proposed amendments further in this Summary.

Following is a summary of the rulemaking history of N.J.A.C. 8:57. The PHC, which was a part of the Department pursuant to N.J.S.A. 26:1A-4 (the Summary above explains the recent change in the role of the PHC) adopted and implemented Chapter 57, Communicable Diseases prior to September 1, 1969 in accordance with N.J.S.A. 26:1A-7. The PHC adopted subchapter 4, Immunization of Pupils in School, as R.1975 d.121, effective May 16, 1975. (7 N.J.R. 154(a), 7 N.J.R. 264(a)). Subchapter 4 established the immunizations required of pupils to attend any school, child care center, preschool or kindergarten in New Jersey and the requirements for appropriate dosing, exemptions, provisional admission, evidence of immunization, provision of

immunization, and record retention. The Department adopted emergency rules at Subchapter 5, New Jersey Influenza Immunization Program, as R.1976 d.315, effective October 8, 1976, in order to establish a framework to deliver the swine influenza immunization to as many persons in New Jersey as possible. (8 N.J.R. 513(a)).

Pursuant to Executive Order No. 66 (1978), the PHC readopted with amendments Subchapter 1, Reportable Communicable Diseases, as R.1980 d.498, effective November 12, 1980. (12 N.J.R. 577(e), 13 N.J.R. 13(b)). The adopted amendments added the following reportable diseases: Kawasaki disease, Reyes disease, Guillain-Barre Syndrome, and Lyme Arthritis and deleted the phrase "unusual manifestations of disease" throughout all the sections. Pursuant to Executive Order No. 66 (1978), the PHC readopted Subchapter 4, Immunization of Pupils in School, as R.1983 d.311, effective July 18, 1983. (15 N.J.R. 781(a), 15 N.J.R. 1253(a)). Pursuant to Executive Order No. 66 (1978), the PHC readopted with amendments Subchapter 1, Reportable Communicable Diseases, as R.1985 d.363, effective June 18, 1985. (17 N.J.R. 784(a), 17 N.J.R. 1764(a)). The proposed amendments intended to add Acquired Immunodeficiency Syndrome (AIDS) and Meningitis, Infectious, etiology: *Hemophilus influenzae* as reportable diseases. However, on adoption the PHC decided not to add AIDS as a reportable disease. It appears that the PHC did adopt AIDS as reportable condition at N.J.A.C. 8:57-1.14 as of October 6, 1986. (21 N.J.R. 3897(a)).

The Department's Division of Epidemiology and Disease Control repealed N.J.A.C. 8:57-1.19 and 1.20 and adopted a new rule at N.J.A.C. 8:57-6 Cancer Registry, as R.1986 d.277, effective June 16, 1986. (17 N.J.R. 2836(b), 18 N.J.R. 1283(a)). The new rule at N.J.A.C. 8:57-6 established a framework for reporting of cancer cases to the Department. The Department recodified with amendments N.J.A.C. 8:57-6, Cancer Registry, as N.J.A.C. 8:57A, by R.1990 d.242, effective May 21, 1990. (21 N.J.R. 3909(a), 22 N.J.R. 1596(a)).

Pursuant to Executive Order No. 66 (1978), the Department readopted with amendments Chapter 57, Communicable Diseases, as R.1990 d.243, effective April 20, 1990, and repealed Subchapter 2, Isolation of Persons Ill or Infected with a Communicable Disease, Subchapter 3, Poliomyelitis Vaccine Records, and Subchapter 5, New Jersey Influenza Immunization Program, by R.1990 d.243, effective June 4, 1990. The Department also repealed N.J.A.C. 8:57-1.13 and 1.14 in order to make those sections separate subchapters with new rules in a different rulemaking. The most substantive amendments that the Department adopted clarified who was required to report communicable diseases, removed specific diseases from the list of reportable diseases, added specific diseases to the list of reportable diseases, added information required in the report of a communicable disease, created new requirements for laboratory reporting, established a section for medical exemptions for school immunizations, established a section for religious exemptions for school immunizations, set forth criteria for provisional admission to schools, set forth new requirements for

Diptheria and tetanus toxoids and pertussis vaccine, and established a new mumps immunization requirement. (21 N.J.R. 3897(a), 22 N.J.R. 1766(a)). The Department adopted new rules at Subchapter 2, Reporting of Acquired Immunodeficiency Syndrome and Infection with Human Immunodeficiency Virus, by R.1990 d.244, effective May 21, 1990, operative June 4, 1990. (21 N.J.R. 3905(a), 22 N.J.R. 1592(a)). Subchapter 2 established a framework for reporting cases of AIDS and Human Immunodeficiency Virus (HIV) to the Department so that appropriate actions could be taken to protect public health and for further planning on the impact these diseases would have on the health care system. The Department adopted new rules at Subchapter 3, Reportable Occupational and Environmental Diseases and Poisons, by R.1990 d.245, effective May 21, 1990, operative June 4, 1990. (21 N.J.R. 3907(a), 22 N.J.R. 1595(a)). Subchapter 3 established a broader framework for reporting cases of occupational and environmental diseases and poisons to the Department so that local and State health departments could investigate causes of these diseases and poisonings and prevent further occurrences.

Pursuant to Executive Order No. 66 (1978), the Department readopted Chapter 57, Communicable Diseases, as R.1995 d.240, effective April 12, 1995. (N.J.R. 420(a), 27 N.J.R. 1987(a)). The Department repealed Subchapter 1, Reportable Communicable Diseases, and adopted Subchapter 1, Reportable Communicable Diseases, as new rules by R.1995 d.277, effective June 5, 1995. (27 N.J.R. 420(a), 27 N.J.R. 2216(a)). The Department adopted new rules at

N.J.A.C. 8:57-1 in order to make changes in language, format, and organization for further clarity. The Department also made changes to streamline the reporting process, add new diseases, and require laboratory submission of certain disease isolates. The Department completed an emergency adoption of new rules at Subchapter 6, Higher Education Immunization, by R.1995 d.518, effective August 21, 1995, to expire October 20, 1995. (27 N.J.R. 3631(a)). The Department completed a concurrent proposal of new rules at Subchapter 6, which was adopted as R.1995 d.587, effective October 20, 1995, with changes effective November 20, 1995. (27 N.J.R. 3631(a), 27 N.J.R. 4701(a)). The Department adopted Subchapter 6 in order to establish immunization requirements for specified undergraduate and graduate students enrolled in a program leading to an academic degree. On July 12, 1994, the Higher Education Restructuring Act of 1994 (P.L. 1994, c. 48) abolished the Department of Higher Education. This Act also amended P.L. 1988, c. 158 (N.J.S.A. 18A:61D-1 et seq.), which required all undergraduate and graduate students born after 1957 and enrolled in a program leading to an academic degree to submit proof of immunization as a condition of admission or continued enrollment, and transferred the Department of Higher Education's authority to regulate student immunization to the Department.

The Department initially proposed new rules at Subchapter 5, Confinement of Persons with Tuberculosis on August 15, 1994, but the Department made necessary revisions to the rule text based on public comments, which could not be accepted on adoption. (26 N.J.R. 3236(a)). The Department

then re-proposed and adopted Subchapter 5, Confinement of Persons with Tuberculosis, as new rules by R.1996 d.130, effective March 18, 1996. (27 N.J.R. 3657(a), 28 N.J.R. 1507(a)). The rules at Subchapter 5 established a framework for effective reporting, monitoring, and control of tuberculosis disease. The Department adopted new rules at Subchapter 7, Student Health Insurance Coverage, as R.1997 d.347, effective August 18, 1997. (29 N.J.R. 2261(a), 29 N.J.R. 3727(a)). On July 12, 1994, the Higher Education Restructuring Act of 1994, N.J.S.A. 18A:61D-1 et seq. abolished the Department of Higher Education. This Act, in pertinent part, also transferred the Department of Higher Education's authority to regulate full-time students' health insurance coverage to the Department. Historically, although vested with such authority, the Department of Higher Education chose not to promulgate rules regarding student health insurance. The Department adopted new rules at N.J.A.C. 8:57-7 so that full-time students at institutions of higher education would have the widest latitude permissible by law in selecting health insurance coverage, but only requiring documentation from the institutions that will provide evidence of compliance with the statute. The Department adopted new rules at Subchapter 8, Childhood Immunization Insurance Coverage, as R.1998 d.434, effective August 17, 1998. (30 N.J.R. 44(a), 30 N.J.R. 3101(a)). In New Jersey, P.L. 1995, c. 316 was enacted January 5, 1996 and became effective April 4, 1996. The purpose of P.L. 1995, c. 316, in part, is to make childhood immunizations more accessible to insured children in New Jersey by mandating health insurance policies or

contracts provide coverage for childhood immunizations. P.L. 1995, c. 316, §§1 through 6 (as codified, N.J.S.A. 17:48E-35.10, 17:48-6m, 17B:27-46.11, 26:2J-4.10, 17B:27A-7 and 17B:27A-19, respectively) require that all health insurance contracts delivered, issued, or renewed in New Jersey provide coverage for childhood immunizations. The adopted rules at N.J.A.C. 8:57-8, promulgated pursuant to section 7 of P.L. 1995, c. 316 (as codified, N.J.S.A. 26:2-137.1), are required to make childhood immunizations more accessible to children in New Jersey.

The Department proposed to readopt with amendments Chapter 57, Communicable Diseases. (32 N.J.R. 965(a)). The Department's most substantive proposed amendments were to add new diseases to the list of reportable diseases, establish different methods of reporting, and clarify procedures for reporting at subchapter 1; require viral load tests to be reported and require reporting of perinatal exposure to HIV at subchapter 2; eliminate reporting to local health and paper reporting to the Department, remove specific reportable conditions and add specific conditions to be reported at subchapter 3; establish a hepatitis B vaccine requirement for Grade 6 pupils by September 1, 2001, and establish vaccine requirements for measles at subchapter 4; add provisions to allow a health officer to intervene in tuberculosis health management earlier in the process at subchapter 5; and establish that children enrolled in the New Jersey KidCare Plan D cannot be charged a co-payment under subchapter 8. Prior to readoption, however, pursuant to Executive Order No. 66 (1978), Chapter 57, Communicable

Diseases, expired on April 12, 2000. The Department adopted Chapter 57, Communicable Diseases, as new rules by R.2000 d.378, effective September 18, 2000. (32 N.J.R. 965(a), 32 N.J.R. 3463(a)).

The Department adopted amendments and a new rule at N.J.A.C. 8:57-6, Higher Education Immunization to require all four-year colleges, except Thomas Edison State College, to provide specific information about meningococcal disease to all new students entering their institution after September 1, 2001 and to establish record retention, reporting, and vaccine administration requirements and/or authorizations regarding meningococcal disease. (33 N.J.R. 2752(a), 34 N.J.R. 3023(a)).

The Department readopted with amendments Chapter 57, Communicable Diseases, as R.2003 d.412, effective September 25, 2003 (readoption) and October 20, 2003 (amendments). (34 N.J.R. 3945(a), 35 N.J.R. 4883(b)) The Department also adopted repeals and new rules at N.J.A.C. 8:57-1.3, 1.4 and 1.5 and adopted a repeal at N.J.A.C. 8:57-1.7. (35 N.J.R. 4883(b)). The Department's most substantive adopted changes through amendments and new rules include revisions to definitions, revisions to the lists of reportable diseases, and changes in laboratory report and culture submission methods at subchapter 1; revisions to expand required reporters at subchapter 2; additional items for required reporting, and confidentiality provisions at subchapter 3; and clarification of persons permitted to document immunizations and write medical

contraindications, and clarification of the Hib conjugate and hepatitis vaccines at subchapter 4. (34 N.J.R. 3945(a), 35 N.J.R. 4883(b)).

The Department adopted amendments and new rules to N.J.A.C. 8:57-4, Immunization of Pupils in Schools in 2008. (38 N.J.R. 5284(a) and 40 N.J.R. 151(a)). The most substantive changes to subchapter 4 include: a clarification of when provisional admission is required; an update to the age requirement for completion of the primary Diptheria, Tetanus, Pertussis and DiptheriaTetanus, acellular Pertusis (DTP/DTaP) vaccine series; a provision permitting temporary suspension by the Commissioner of an immunization requirement for the particular immunization affected by a vaccine supply shortage; clarification of the acceptable dosing timeframe for a legitimate dose of vaccine; a new requirement for pneumococcal conjugate vaccine series; a new requirement for an annual dose of influenza vaccine; a new requirement for children born after January 1, 1996 and enrolled in Grade Six or transferring into a New Jersey school from another state or country to receive one dose of the tetanus, diptheria, acellular pertusis (Tdap) vaccine; and a new requirement for children born after January 1, 1996 and enrolled in Grade Six or transferring into a New Jersey school from another state or country to receive and one dose of meningococcal vaccine. The amendments and new rules would not be operative until September 1, 2008, except for the clarification of the acceptable dosing timeframe for a legitimate dose of vaccine, which became operative on January 7, 2008. (38 N.J.R. 5284(a), 40 N.J.R. 151(a)).

Following is a summary of the rules proposed for readoption and the proposed amendments, repeals and new rules:

N.J.A.C. 8:57-1: Reportable Communicable Diseases

The rules proposed for readoption at N.J.A.C. 8:57-1 would continue to set forth the purpose and scope of the rules at subchapter 1, provide definitions for clarity of the words and terms used in the rules, establish the reportable communicable diseases, and establish the timeframes, methods of reporting and persons required to report to the Department. The rules proposed for readoption at N.J.A.C. 8:57-1 would continue to establish guidelines for isolation and quarantine, medical examination and specimen submission for persons with communicable diseases. The rules proposed for readoption at N.J.A.C. 8:57-1 would continue to set forth guidelines regarding foodhandlers ill or infected with a communicable disease. The rules proposed for readoption at N.J.A.C. 8:57-1 would also continue to establish requirements for confidentiality of communicable disease reports and for enforcement.

The Department proposes amendments throughout N.J.A.C. 8:57-1 to make grammatical, technical, and formatting changes in order to better articulate the requirements of the rules. The Department proposes amendments at N.J.A.C. 8:57-1.1(a) through (c) to better articulate the purpose and scope of the rules. The Department proposes amendments at N.J.A.C. 8:57-1.1(d) and (e) to set forth the Commissioner's authority to amend the reportable communicable diseases under subchapter 1 as necessary to control disease or to amend any provision of the

chapter during a public health emergency. The Department proposes an amendment at N.J.A.C. 8:57-1.1(f) to establish that the Department's Communicable Disease Service is a public health entity with public health oversight functions pursuant to the Health Insurance Portability and Accountability Act of 1996, 45 CFR §§164.501 and 164.512(b), referred to as HIPAA.

The Department proposes new rules at new N.J.A.C. 8:57-1.2 to set forth, in one central location, the materials that the Department is incorporating by reference in this subchapter. The Department incorporates by reference in this subchapter the Electronic Laboratory Reporting Technical Manual, written and published by the New Jersey Department of Health and Senior Services, Communicable Disease Service and the Office of Information Technology Services, available at proposed new Subchapter 1 Appendix A, which provides technical guidance on the electronic transmission of data to the Department.

The Department proposes to recodify existing N.J.A.C. 8:57-1.2 as 1.3, amend this section to make the definitions applicable to the entire chapter, and add the following definitions to provide better clarity of the rules: "administrator," "animal facility," "certified animal control officer," "clinical laboratory," "clinical laboratory director," "domestic companion animal," "electronic laboratory reporting," "health care facility," "Hospital-onset methicillin-resistant *Staphylococcis aureus* (MRSA)," "Influenza virus, novel strain," "isolation," "kennel," "Methicillin-resistant *Staphylococcis aureus* (MRSA)," "Multidrug-

resistant organisms," "neonatal," "overlap agent or toxin," "pediatric," "pet shop," "pound," "public health emergency," "quarantine," "shelter," "Vancomycin-intermediate Staphylococcus aureus, and Vancomycin-resistant Staphylococcus aureus," "veterinarian," and "Zoonotic disease."

The Department proposes amendments to revise the following definitions to provide better clarity and in some instances to be consistent with existing definitions of the following words and terms as stated in other State laws: "bioterrorism," "child care center," "Commissioner," "electronic reporting," "health officer," "health care provider," nosocomial infection," and "outbreak."

The Department proposes amendments to delete the following definitions because they are no longer used in the rules or are not necessary: "Hospital or other health care institution," "N.J.A.C.," and "N.J.S.A."

The Department proposes to amend N.J.A.C. 8:57-1.4 to rename and re-organize this section and update defined terms, without effecting a substantive change in meaning, to provide better clarity for the regulated community on reporting responsibilities.

The Department proposes to recodify existing N.J.A.C. 8:57-1.3 as 1.5, and to amend the name of this section to specify that the section covers reportable communicable diseases. The Department proposes amendments to reorganize the list of reportable communicable diseases to clearly delineate those diseases that are immediately reportable by telephone and those diseases that are reportable within 24 hours of diagnosis. The Department proposes amendments at

recodified N.J.A.C. 8:57-1.5(a) too add Sars-CoV Disease (SARS); influenza, novel strains only; and all cases of acute Hepatitis A (currently only those cases in institutional settings are immediately reportable) because these illnesses require immediate public health action to prevent further spread of illness. The Department proposes amendments at recodified N.J.A.C. 8:57-1.5(b) to add Influenza-associated pediatric mortality; *Staphylcoccus aureus*, with intermediate- (VISA) or high-level-resistance (VRSA) to vancomycin; Streptococcal toxic-shock syndrome; and Varicella (chicken pox) to the list of diseases reportable within 24 hours of diagnosis because they are on the CDC list of nationally notifiable diseases, cause significant morbidity, and there are public health actions that can be taken to prevent the spread of illness when public health notification is made. The Department proposes an amendment at recodified N.J.A.C. 8:57-1.5(a) to list Hantavirus infection as Hantavirus pulmonary syndrome. The Department proposes amendments at recodified N.J.A.C. 8:57-1.5(b) to list Enterohemorrhagic *Escherichia coli* as *Escherichia coli* shiga toxin producing strains (STEC) only; Granuloma inguinale (Calymmatobacterium granulomatis) as Granuloma inguinale (Klebsiella granulomatis); Hemolytic uremic syndrome as Hemolytic uremic syndrome, post diarrheal; Hepatitis B including Hepatitis B surface antigen test positive in a pregnant woman as Hepatitis B, newly diagnosed acute, perinatal and chronic infections, and pregnant women who have tested positive for Hepatitis B surface antigen; Hepatitis C as Hepatitis C, acute and chronic, newly diagnosed cases only; Legionellosis

(*Legionella pneumophila*) as Legionellosis (*Legionella spp.*); Syphilis primary, and secondary as Syphilis, all stages; Toxic Shock syndrome as Toxic Shock Syndrome (other than Streptococcal); Trichinosis as Trichinellosis; and Vibrio infections other than cholera as Vibriosis for better clarity on what specific diseases are reportable. The Department proposes amendments at recodified N.J.A.C. 8:57-1.5(b) to delete Dengue fever, Guillain–Barre syndrome, Hepatitis A, and Kawasaki disease from the list of diseases reportable within 24 hours because they are no longer considered diseases of public health significance.

The Department proposes an amendment at recodified N.J.A.C. 8:57-1.5(c) to add a new requirement that health care providers and administrators report to the Department all cases of persons who harbor or are suspected of harboring any illness or health condition that may be reasonably believed to be a potential cause of a public health emergency, as set forth in the Emergency Health Powers Act at N.J.S.A. 26:13-4.

The Department proposes an amendment at recodified N.J.A.C. 8:57-1.5(d) to add a new requirement pursuant to N.J.S.A. 26:2H-12.35 through 12.38 (P.L.2007, c.120). Section 1.5(d) would require that administrators of general hospitals licensed by the Department in accordance with N.J.S.A. 26:2H-1 et seq., and as classified in the Hospital Licensing Standards at N.J.A.C. 8:43G-1.2 and 1.3(b), report monthly: (1) The number of cases of hospital-onset MRSA bloodstream infections per 1000 patient days by hospital unit where active surveillance testing for MRSA is being performed, and (2) The percentage of

eligible patients who have a MRSA surveillance test performed on admission to a hospital unit where active surveillance testing for MRSA is being performed. Section 1.5(d) would require hospital administrators to complete the reporting through a web-based interface to be developed and communicated by the Department.

The Department proposes to recodify existing N.J.A.C. 8:57-1.5 as 1.6, and proposes amendments to rename and re-organize this section, without effecting a substantive change in meaning except as noted below, to provide better clarity for the regulated community on how and what information to report.

The Department proposes an amendment at recodified N.J.A.C. 8:57-1.6(b) to add electronic reporting as an acceptable method of communicable disease reporting for health care providers and administrators.

The Department proposes amendments at recodified N.J.A.C. 8:57-1.6(c) to add the following two new requirements to the content of a communicable disease report from health care providers and administrators: clinical laboratory data which supports the diagnosis, and any treatment provided (for sexually transmitted diseases only). This information is needed to formulate and implement the public health response to each reported case of illness.

The Department proposes an amendment at recodified N.J.A.C. 8:57-1.6(e) to add a new requirement that health care providers and administrators report to the Department all cases of persons who harbor or are suspected of harboring any illness or health condition that may be reasonably believed to be a

potential cause of a public health emergency, as set forth in the Emergency Health Powers Act at N.J.S.A. 26:13-4.

The Department proposes to recodify existing N.J.A.C. 8:57-1.6 as 1.7, and proposes amendments to re-organize this section, without effecting a substantive change in meaning except as noted below, to provide better clarity for clinical laboratory directors on how and what information to report.

The Department proposes amendments to re-organize the list of reportable positive laboratory results denoting disease to more clearly delineate those that are immediately reportable by telephone, and those that are reportable within 24 hours of diagnosis. The Department proposes amendments at recodified N.J.A.C. 8:57-1.7(a) to add Sars-CoV Disease (SARS) and Hepatitis A to the list of immediately reportable diseases because these illnesses require immediate public health action to prevent further spread of illness. The Department proposes amendments at recodified N.J.A.C. 8:57-1.7(b) to add Influenza isolates for laboratories reporting electronically; Klebsiella granulomatis; *Staphylcoccus aureus*, with intermediate-(VISA) or high-level-resistance (VRSA) to vancomycin; and Varicella virus except IgG tests to the list of diseases reportable within 24 hours of diagnosis because they are on the CDC list of nationally notifiable diseases, cause significant morbidity, and there are public health actions that can be taken to prevent the spread of illness when public health notification is made. The Department proposes amendments to recodified N.J.A.C. 8:57-1.7(b) to list *Escherichia coli* O157:H7 and other hemorrhagic strains as *Escherichia*

coli, shigatoxin producing strains (STEC) only; *Legionella pneumophila as Legionella spp.*; *Mycobacterium tuberculosis* as *Mycobacterium tuberculosis*, including antibiotic sensitivity tests for *M. tuberculosis*; *Streptococcus pneumoniae* isolate from cerebrospinal fluid, blood, or any other normally sterile site as *Streptococcus pneumoniae* isolate from cerebrospinal fluid, blood, or any other normally sterile site, and antimicrobial susceptibility test results, if performed; and *Streptococcus agalactiae*, Group B, perinatal has as *Streptococcus agalactiae*, Group B, neonatal; for better clarity in what is reportable.

The Department proposes an amendment at recodified N.J.A.C. 8:57-1.7(c) to add the following three new requirements to the content of a communicable disease report from clinical laboratory directors: the source or type of specimen tested, the date the specimen was collected, and the telephone number of the health care provider submitting the specimen. This information is necessary to formulate and implement the public health response to each reported case of illness.

The Department proposes amendments at N.J.A.C. 8:57-1.7(a)3 and (b)3 to add a new requirement that effective September 1, 2010, clinical laboratory directors must report reportable communicable diseases only through electronic laboratory reporting as stated in the rule. Electronic data exchange is becoming an industry standard, and electronic laboratory reporting of reportable disease data will significantly decrease the time and effort currently required by the handling

of paper reports and will improve the timeliness of public health disease prevention and control efforts through more efficient data exchange.

The Department proposes amendments at recodified N.J.A.C. 8:57-1.7(e) to revise the list of laboratory isolates that clinical laboratory directors are required to submit to the Department's Public Health and Environmental Laboratory to reflect more current terminology and organisms of current public health concern. The Department proposes to add Vancomycin-intermediate Staphylococcus aureus (VISA) and vancomycin-resistant Staphylococcus aureus (VRSA), and Multidrug-resistant organisms upon the request of the Department. The Department proposes to delete Streptococcus pyogenes, penicillin-reisistant Streptococcus pneumoniae, Vancomycin-resistant Enterococcus spp., Glycopeptide resistant Staphylococcus spp. and Streptococococcus spp., and multiple antibiotic resistant bacteria (upon request). The Department proposes to add "enrichment broths containing shiga toxin producing E.coli" to Escherichia coli 0157:H7.

The Department proposes an amendment at recodified N.J.A.C. 8:57-1.7(g) to add a new requirement that clinical laboratory directors submit an annual report summarizing the antibiotic resistant organisms that have been identified within the laboratory. This requirement would replace the existing requirement for monthly submission of an Epidemiology Surveillance form, which the Department is deleting.

The Department proposes an amendment at N.J.A.C. 8:57-1.7(h) to add a new requirement that clinical laboratory directors who send specimens to other clinical laboratories for testing are responsible for submitting the results of those tests to the Department. The Department is proposing this amendment to ensure that all reportable disease information collected within New Jersey is properly reported to the Department.

The Department proposes a new rule at new N.J.A.C. 8:57-1.8 covering the reporting of zoonotic diseases and any disease outbreaks in domestic companion animals (DCAs) by veterinarians, certified animal control officers, and animal facility management. These zoonotic diseases are easily transmissible from animals to humans, cause significant morbidity, and there are public health actions that can be taken to prevent the spread of illness when public health notification is made. The proposed new reportable zoonotic diseases at proposed N.J.A.C. 8:57-1.8(a) include Anthrax, Avian Chlamydiosis, *Brucella canis*, Campylobacteriosis, *Escherichia coli* shiga toxin producing strains (STEC) only, *Giardia lamblia* (oocyst positive only), Leishmaniasis, Leptospirosis, Lymphocytic choriomeningitis, *Mycobacterium tuberculosis*, Plague, Q Fever, Salmonellosis, and Tularemia. Proposed new N.J.A.C. 8:57-1.8(b) would establish the requirement for reporting animals suspected or confirmed with rabies pursuant to N.J.A.C. 8:23-1.2 and proposed N.J.A.C. 8:57-1.8(c) would require the reporting of any outbreak or suspected outbreak. The proposed new N.J.A.C.

8:57-1.8(d) and (e) would establish the method of reporting and the content of the report respectively.

Reporting of these specific zoonotic diseases and disease outbreaks in domestic companion animals by veterinarians, certified animal control officers, and animal facility managers to public health officials is necessary to prevent the transmission of disease between pets and people through appropriate public health intervention. The proposed animal reporting rules apply only to diseases diagnosed in DCAs and specifically exempt communicable diseases diagnosed in livestock, thus supplementing the New Jersey Department of Agriculture (NJDA) livestock and poultry disease surveillance, testing, sampling, detection and investigation activities, as set forth in N.J.S.A. 4:5. Proposed new N.J.A.C. 8:57-1.8(h) would articulate that the Department shall notify the Department of Environmental Protection or Secretary of Agriculture of any report made pursuant to this subchapter where the Commissioner suspects conditions that could potentially affect animals, plants or crops under the jurisdiction of the Department of Environmental Protection or Department of Agriculture.

The Department proposes to recodify existing N.J.A.C. 8:57-1.7 as 1.9, and proposes amendments to re-organize this section, without effecting a substantive change in meaning except as noted below, to provide better clarity for health officers on how and what to report. The Department proposes an amendment at recodified N.J.A.C. 8:57-1.9(b) to add a new requirement that health officers submit the reports of their investigations electronically to the

Department, except for those on sexually transmitted diseases and tuberculosis. Electronic data exchange is becoming an industry standard, and electronic reporting of disease investigations will significantly decrease the time and effort currently required by the handling of paper reports and it will improve the timeliness of public health disease prevention and control efforts through more efficient data exchange.

The Department proposes to recodify existing N.J.A.C. 8:57-1.8 as 1.10, and proposes amendments to re-organize this section, without effecting a substantive change in meaning except as noted below, to provide better clarity for health officers on conducting health officer investigations. The Department proposes an amendment at recodified N.J.A.C. 8:57-1.10 to add a new requirement that health officers follow direction given by the Department when performing health officer investigations. It is essential that all jurisdictions follow a single plan of public health action in response to a communicable disease report. It is reasonable for the Department to formulate and direct the public health response to reportable communicable diseases. The Department proposes an amendment at recodified N.J.A.C. 8:57-1.10(f) to add a new requirement that during outbreak investigations involving more than one health jurisdiction, the Department shall coordinate the investigation. It is now quite common for public health problems to involve more than one local public health jurisdiction, and it is essential that all jurisdictions follow a single plan of public health action. It is reasonable for the Department to formulate and lead the public health response to

a multi-jurisdictional disease problem. The Department proposes an amendment at recodified N.J.A.C. 8:57-1.10(g) to add a new requirement that the health officer shall establish quarantine, test and transport procedures for pet birds infected with, or exposed to, avian chalamydiosis in the manner set forth at N.J.A.C. 8:23-1.4. The Department proposes an amendment at recodified N.J.A.C. 8:57-1.10(h) to articulate the Commissioner's authority to exercise his or her jurisdiction, responsibility, and authority during a public health emergency pursuant to N.J.S.A. 26:13-3(c).

The Department proposes to recodify existing N.J.A.C. 8:57-1.9 as 1.11, and proposes technical amendments to re-organize this section, without effecting a substantive change in meaning, to provide better clarity on isolation and quarantine for the regulated community. At recodified N.J.A.C. 8:57-1.11(a)3 the Department references the Quarantine and Isolation-Model Rules for Local Boards of Health, written and published by the Department's Communicable Disease Service, as a guide for establishing isolation and quarantine measures, which is available in proposed new Subchapter 1 Appendix B.

The Department proposes to recodify existing N.J.A.C. 8:57-1.10 as 1.12, and proposes technical amendments to re-organize this section, without effecting a substantive change in meaning, to provide better clarity on medical examination and specimen submission for the regulated community.

The Department proposes to recodify existing N.J.A.C. 8:57-1.11 as 1.13, and proposes amendments to re-organize this subsection, without effecting a

substantive change in meaning, to provide better clarity for the regulated community on handling foodhandlers ill or infected with communicable diseases..

The Department proposes to recodify existing N.J.A.C. 8:57-1.12 as 1.14, and proposes amendments to re-organize and expand this subsection, without effecting a substantive change in meaning, to provide better clarity for the regulated community. In particular, the Department proposes to remove existing subsection (b) and replace it with a new subsection that sets forth the confidentiality of information that the Department shares with the Secretary of Agriculture involving an overlap agent or toxin in accordance with N.J.S.A. 26:13-3d. The Department proposes an amendment at recodified N.J.A.C. 8:57-1.14 to recodify subsection (c) as subsection (d) and to add a new subsection (c) to articulate that the reports and forms submitted to the Department pursuant to subchapter 1 are not government records subject to public access or inspection within the meaning of N.J.S.A. 47:1A-1 et seq.

The Department proposes a new rule at N.J.A.C. 8:57-1.15 to provide better clarity for the regulated community on how the Department will enforce this subchapter. The Department proposes to remove enforcement provisions in existing sections throughout subchapter 1 and include them in this new proposed section. Individuals and institutions who fail to report pursuant to the requirements of this subchapter would be subject to a fine. Individuals and institutions may receive from the Department a warning letter to comply, and if

they continue to fail to comply, that failure may be reported to the licensing authority, where applicable, or to the regulatory authority, where applicable.

N.J.A.C. 8:57-2: Reporting of Acquired Immunodeficiency Syndrome and infection with Human Immunodeficiency Virus

The rules proposed for readoption at N.J.A.C. 8:57-2 have and would continue to set forth the timeframes, methods of reporting, and persons required to report individuals found to be infected with Human Immunodeficiency Virus (HIV) and Acquired Immunodeficiency Syndrome (AIDS) to the Department. The rules proposed for readoption at N.J.A.C. 8:57-2 would continue to set forth the timeframes, methods of reporting and persons required to report children perinatally exposed to HIV. The rules proposed for readoption at N.J.A.C. 8:57-2 would continue to establish requirements for testing procedures for HIV, access to information submitted to the Department pursuant to N.J.A.C. 8:57-2, and enforcement provisions applicable to those that fail to comply with the requirements of this subchapter.

The Department proposes amendments throughout N.J.A.C. 8:57-2 to make grammatical, technical, and formatting changes in order to better articulate the requirements of the rules and make changes to utilize new definitions. The Department also proposes repeals and new rules and as a result, there are proposed recodifications.

The Department proposes to repeal N.J.A.C. 8:57-2.1 and replace this section with new rules. The proposed new rules would establish the purpose and

scope of the subchapter. Proposed new N.J.A.C. 8:57-2.1(a) would set forth that the purpose of this subchapter is to establish a framework for the reporting of HIV and AIDS as well as to maintain standards of confidentiality in accordance with N.J.S.A. 26:1A-7, N.J.S.A. 26:5C-1 et seq., particularly 26:5C-6 and 26:5C-20. Proposed new N.J.A.C. 8:57-2.1(b) would establish that the subchapter applies to health care providers, institutions, and clinical laboratories that perform tests indicative of HIV and AIDS. Proposed new N.J.A.C. 8:57-2.1(c) would retain language at existing N.J.A.C. 8:57-2.1(a) and state that the provisions of N.J.A.C. 8:57-1 do not apply to cases of AIDS or infection with HIV.

The Department proposes to recodify existing N.J.A.C. 8:57-2.2 as N.J.A.C. 8:57-2.4, which is discussed in this summary at recodified N.J.A.C. 8:57-2.4. The Department proposes a new rule at N.J.A.C. 8:57-2.2 that would set forth the documents incorporated by reference in this subchapter. The Department proposes to incorporate by reference, as amended and supplemented, the Centers for Disease Control and Prevention of the United States Public Health Services case definitions of HIV and AIDS available in Volume 41 No. RR-17 of the Morbidity and Mortality Weekly Report (MMWR) published on December 18, 1992 and in Volume 43 No RR-17 of the MMWR published on September 30, 1994 and updates found at www.cdc.gov/mmwr. The Department proposes to incorporates by reference the following forms and instructions in this subchapter: Adult HIV/AIDS Confidential Case Report (DHAS-44) (Appendix A) a form required for health care providers and responsible parties to report adult cases of

HIV and AIDS; HIV/AIDS Laboratory Report (DHAS-43) (Appendix B) a form required for clinical laboratory directors to report tests defined in this subchapter; Pediatric HIV/AIDS Confidential Case Report (DHAS-45) (Appendix C) a form required for health care providers and responsible parties to report pediatric cases of HIV, AIDS and pediatric exposures to HIV; The HIV Test Form (OMB No. 0920-0696 Exp. Date: 08/31/2010), as amended and supplemented, produced by the Centers for Disease Control and Prevention (Appendix D) required for health care providers or responsible parties using the State Public Health and Environmental Laboratories to perform HIV testing in order to report adult cases of HIV and AIDS; Instructions for HIV Reporting using the HIV Test Form (Appendix E) to be used by health care providers or responsible parties testing individuals as part of the New Jersey HIV Counseling and Testing System and using the New Jersey Public Health and Environmental Laboratories; The Instructions for Submission of Positive HIV Diagnostic Specimens (Appendix F) is a set of instructions to be used by health care providers, responsible parties and clinical laboratory directors for sending specimens to the New Jersey Public Health and Environmental Laboratories; and Instructions for Electronic Submission of Laboratory Results Indicative of HIV Infection (Appendix G) in this subchapter, which details the requirements for clinical laboratory directors to report tests defined in this subchapter.

The Department proposes to add a new rule at N.J.A.C. 8:57-2.3, which would define words and terms used throughout the subchapter. The Department

has modified several of the terms at the existing N.J.A.C. 8:57-2.1 to provide technical corrections and clarity and has included them at proposed new N.J.A.C. 8:57-2.3. Those defined terms are "Aquired Immunodeficiency Syndrome or AIDS," "audit," "CD4 Count," "division," "epidemiologic investigations," "Human Immunodeficiency Virus or HIV," "institution," "Laboratory HIV results," "perinatally exposed," and "responsible party." In addition, the proposed definitions of HIV and AIDS incorporate by reference, as amended and supplemented, the case definitions of HIV and AIDS established by the Centers of Disease Control and Prevention (CDC) of the United States Public Health Services published in Volume 41 No. RR-17 of the Morbidity and Mortality Weekly Review (December 18, 1992) and Volume 43 No. RR-17 (September 30, 1994). A copy of these publications is available at the CDC website at www.cdc.gov/mmwr.

The Department proposes to recodify existing N.J.A.C. 8:57-2.2 as 2.4. Existing N.J.A.C. 8:57-2.2 has and recodified N.J.A.C. 8:57-2.4 would continue to set forth the requirements of and methods for reporting HIV infection to the Department. The Department proposes to amend the title of recodified N.J.A.C. 8:57-2.4 to add health care providers and responsible parties, which are proposed new terms. At recodified N.J.A.C. 8:57-2.4(a) the Department proposes amendments to remove the term physician and replace it with proposed new language, health care provider and responsible party. At section 2.4(a) the Department proposes an amendment to remove a reference to AIDS because this

section is about HIV and an amendment to remove the discussion about the content of the HIV report, the language preventing duplicate reporting, and the provision on collection of information by the Department. The Department proposes an amendment at section 2.4(a) to set forth the required form, the Adult HIV/AIDS Confidential Case Report, set forth at proposed subchapter 2 Appendix A. At recodified N.J.A.C. 8:57-2.4(b), the Department proposes an amendment to add reporting requirements for health care providers or responsible parties that are part of the New Jersey HIV Counseling and Testing System and that use the PHEL. The health care providers or responsible parties would report using the HIV Test form produced by the Centers for Disease Control and Prevention, set forth in proposed subchapter 2 Appendix D. The health care providers or responsible parties would be required to use the Instructions for the HIV Test form, set forth in proposed subchapter 2 Appendix E. The Department proposes an amendment to delete the provisions of existing N.J.A.C. 8:57-2.2(b) that set forth the reporting requirements for institutions, the content of the report and the language preventing duplicate reporting. The Department proposes an amendment to maintain the existing language at N.J.A.C. 8:57-2.2(b), regarding the delegation of HIV reporting requirements, as a new subsection at proposed recodified N.J.A.C. 8:57-2.4(c), which would establish that a health care provider or responsible party may delegate reporting responsibilities. The Department proposes an amendment at recodified N.J.A.C. 8:57-2.4(d) to set forth the circumstances for health care providers and responsible parties to make available

to the Department the names of individuals infected with HIV and their medical records for audit or epidemiological purposes.

The Department proposes to amend existing N.J.A.C. 8:57-2.2(c) to create an entirely new section at recodified N.J.A.C. 8:57-2.5 as discussed below. The proposed new section would be entitled Reporting HIV Infection for Clinical Laboratories at recodified N.J.A.C. 8:57-2.5. The Department proposes to amend recodified N.J.A.C. 8:57-2.5(a) to remove the terms "every, PCR (viral load) test" and replace it with new language. The new language at recodified N.J.A.C. 8:57-2.5(a) would add the terms "a clinical laboratory director and Polymerase Chair Reaction (PCR) also known as a viral load test." The Department proposes an amendment to delete the provisions of existing N.J.A.C.8:57-2.2(c) on the reporting requirements for clinical laboratories, the content of the reporting and language preventing duplicate reporting. Proposed new recodified N.J.A.C. 8:57-2.5(a)(1) and (2) would require use of the Instructions for Electronic Submission of Laboratory Results Indicative of HIV Infection set forth in proposed subchapter 2 Appendix G and the HIV/AIDS Laboratory Report Form (DHAS-43), set forth at proposed subchapter 2 Appendix B. The proposed amendment at recodified N.J.A.C. 8:57-2.5(b) would stipulate that a clinical laboratory director shall report specimens sent to the laboratory from a health care provider, institution or residents of New Jersey.

The Department proposes to recodify existing N.J.A.C. 8:57-2.3 as N.J.A.C. 8:57-2.6. Existing N.J.A.C. 8:57-2.3 and recodified N.J.A.C. 8:57-2.6

would continue to set forth the requirements of and methods for reporting children perinatally exposed to HIV infection to the Department. At recodified N.J.A.C. 8:57-2.6(a) the Department proposes amendments to remove the term physician and replace it with the proposed new language health care provider and responsible party. The Department proposes an amendment at section 2.6(a) to set forth the requirement for reporting perinatally exposed HIV using the Pediatric HIV/AIDS Case Report Form, set froth at proposed subchapter 2 Appendix C. At recodified N.J.A.C. 8:57-2.6(a), the Department proposes an amendment to maintain the existing language at N.J.A.C. 8:57-2.3(b) that sets forth the reporting requirements for institutions, the content of the report, and the language preventing duplicate reporting. The Department proposes an amendment at existing N.J.A.C. 8:57-2.3(b), regarding the delegation of reporting children perinatally exposed to HIV infection, as a new subsection at proposed recodified N.J.A.C. 8:57-2.6(b), which would establish that a health care provider or responsible party may delegate reporting responsibilities. The Department proposes an amendment at recodified N.J.A.C. 8:57-2.6(c) to set forth the circumstances for when a health care provider shall make available to the Department the names of children exposed perinatally to HIV and their medical records for audit or epidemiological purposes.

The Department proposes to recodify existing N.J.A.C. 8:57-2.4 on Reporting AIDS as N.J.A.C. 8:57-2.7. Existing N.J.A.C. 8:57-2.4 has and recodified N.J.A.C. 8:57-2.7 would continue to set forth provisions on reporting

requirements, and the methods used by health care providers and responsible parties of institutions to report AIDS cases. The Department proposes to amend the title of existing N.J.A.C.8:57-2.4 and replace it with a new title at recodified N.J.A.C. 8:57-2.7 on the reporting of AIDS by adding health care providers and responsible parties. At recodified N.J.A.C. 8:57-2.7(a) the Department proposes amendments to remove the term physician and replace it with a health care provider or responsible party. The Department proposes an amendment to delete the reference to HIV in existing N.J.A.C. 8:57-2.4(a) since this section is about reporting AIDS and add an amendment to report AIDS using the Adult HIV/AIDS Confidential Case Report Form (DHAS-44) set forth at proposed subchapter 2 Appendix A, at recodified N.J.A.C. 8:57-2.7(a). The Department proposes an amendment to maintain the existing language at N.J.A.C. 8:57-2.4(b), regarding the delegation of AIDS reporting requirements as a new subsection at proposed recodified N.J.A.C. 8:57-2.7(b), which would allow a health care provider or responsible party to delegate the tasks of reporting an AIDS case. Similarly, the Department proposes an amendment at the existing N.J.A.C. 8:57-2.4(b) regarding both AIDS and HIV reporting, as a new subsection at proposed recodified N.J.A.C. 8:57-2.7(c) to stipulate that a health care provider or responsible party shall report regardless of whether the patient previously had been reported as having HIV. At recodified N.J.A.C. 8:57-2.7(d) the Department proposes an amendment to require that a report of AIDS shall also be a report of HIV infection. The Department proposes an amendment to delete the provisions

of existing N.J.A.C. 8:57-2.4(b) on the reporting requirements for AIDS, the content of the report and the language preventing duplicate reporting. The Department proposes an amendment at recodified N.J.A.C. 8:57-2.7(e) to set forth the circumstances for health care providers and responsible parties to make available to the Department the names of individuals infected with AIDS along with their medical records for audit or epidemiological purposes.

The Department proposes to recodify existing N.J.A.C. 8:57-2.4(c) as N.J.A.C. 8:57-2.8. Existing N.J.A.C. 8:57-2.4(c) has and recodified N.J.A.C. 8:57-2.8 would continue to set forth the requirements on the methods for reporting a CD4 count by a clinical laboratory to the Department. At recodified N.J.A.C. 8:57-2.8(a) the Department proposes an amendment to change the term clinical laboratory to clinical laboratory director. The Department proposes an amendment at recodified N.J.A.C. 8:57-2.8(a) to delete the discussion about the submission and content of the AIDS report by a clinical laboratory director to the Department. Proposed new N.J.A.C. 8:57-2.8(a)1 would require use of the Instructions for Electronic Submission of Laboratory Results, available at proposed subchapter 2 Appendix G. Proposed new N.J.A.C. 8:57-2.8(a)2 would require use of the HIV/AIDS Laboratory Report Form (DHAS-43), available at proposed subchapter 2 Appendix B. The Department proposes to delete the reference to specimens sent from physicians' offices and institutions at existing N.J.A.C. 8:57-2.4(c) and replace this with a new subsection at recodified N.J.A.C.

8:57-2.8(b), which would require the reporting of specimens sent to a clinical laboratory in New Jersey.

The Department proposes to recodify existing N.J.A.C. 8:57-2.5 as N.J.A.C. 8:57-2.9. Existing N.J.A.C. 8:57-2.5 has and recodified N.J.A.C. 8:57-2.9 would continue to set forth the testing procedures for HIV. At recodified N.J.A.C. 8:57-2.9(a) the Department proposes to remove the term physician or institution and add health care provider or responsible party. The Department proposes an amendment to delete the provisions of existing N.J.A.C. 8:57-2.5 regarding information on the name and address of a person requesting testing. The proposed amendment at recodified N.J.A.C. 8:57-2.9(a)1 would set forth the requirements for a health care provider or responsible party to not report the name and address of an individual requesting testing, when the individual does not provide his or her name at the testing site.

The Department proposes to repeal existing N.J.A.C. 8:57-2.6, Exceptions to Communicable Disease Classification of AIDS and HIV. The Department believes that it is appropriate to repeal this section because the section is duplicative of existing State and Federal laws that provide civil right protections to persons with HIV and AIDS. This section is no longer necessary or, responsive to the reasons for which it was originally promulgated, in light of protections established since promulgation.

The Department proposes to add a new rule at N.J.A.C. 8:57-2.10, which would describe the process for the submission and handling of HIV specimens.

Proposed new N.J.A.C. 8:57-2.10(a) would explain that health care providers, responsible parties and clinical laboratory directors are required to submit remnant specimens from positive HIV diagnostic tests to the PHEL for further testing. Proposed new N.J.A.C. 8:57-2.10(a)1 sets forth the criteria for identifying and linking specimens sent from the laboratories to the PHEL in accordance with N.J.A.C. 8:57-2.5 and 2.8. Proposed new N.J.A.C. 8:57-2.10(a)2 requires that a specimen shall be sent in accordance with the Instructions for Submission of Positive HIV Diagnostic Specimens available at proposed subchapter 2 Appendix F. Proposed new N.J.A.C. 8:57-2.10(b) would explain the circumstances for when a health care provider or responsible party shall not send a specimen to the PHEL.

The Department proposes to recodify existing N.J.A.C. 8:57-2.7 as N.J.A.C. 8:57-2.11. Existing N.J.A.C. 8:57-2.7 has and recodified N.J.A.C. 8:57-2.11 would continue to set forth the requirements for access to information reported to the Department. The Department proposes amendments at recodified N.J.A.C. 8:57-2.11(a) to articulate that the forms submitted to the Department pursuant to subchapter 2 are not government records subject to public access or inspection within the meaning of N.J.S.A. 47:1A-1 et seq. The Department proposes an amendment at recodified N.J.A.C. 8:57-2.11(c) that would allow the Department to release information without identifiers for reports and epidemiologic profiles.

The Department proposes to recodify existing N.J.A.C. 8:57-2.8 as N.J.A.C. 8:57-2.12. Existing N.J.A.C. 8:57-2.8 and recodified N.J.A.C. 8:57-2.12 would continue to set forth the provisions for failure to comply with the reporting requirements. At recodified N.J.A.C. 8:57-2.12(a) the Department proposes amendments to remove the term physicians and replace it with health care providers. The Department proposes an amendment to maintain the existing language at N.J.A.C. 8:57-2.8(a), regarding the fines for failure to requirement, as a new subsection at proposed recodified N.J.A.C. 8:57-2.12(a)1, which would specify the fines allowed by N.J.S.A. 26:4-129 and 4-130. The Department proposes an amendment to delete the provisions of existing N.J.A.C. 8:57-2.8 for those whose failure to report is determined by the Department to hinder public health and replace this with a new subsection at recodified N.J.A.C. 8:57-2.12(a)2, which would incorporate health care providers. The Department proposes an amendment at recodified N.J.A.C. 8:57-2.12(b) to remove the term "person having control or supervision" and replace it with the proposed new term responsible party. At proposed recodified N.J.A.C. 8:57-2.12(b)1 the Department proposes an amendment to remove the term superintendents and replace this with the new term responsible party and add an amendment to include the reference about reporting fines in accordance with N.J.S.A. 26:4-1.30. The Department proposes an amendment to delete the provisions of existing N.J.A.C. 8:57-2.8(b) that specify "those whose failure to report is determined by the Department to have significantly hindered public health control measures" and replace this with

a new subsection at recodified N.J.A.C. 8:57-2.12(b)2 which would stipulate that a responsible party shall be subject to notification of the Department's Health Facilities Evaluation and Licensing Division for failure to report. The Department proposes an amendment at recodified N.J.A.C. 8:57-2.12(c) to remove the old term supervisors and replace it with clinical laboratory directors. The Department proposes an amendment at recodified N.J.A.C. 8:57-2.12(c)1 that replaces the term supervisors with clinical laboratory directors and adds a reference pertaining to fines for failure to report at N.J.S.A. 26:4-130. At recodified N.J.A.C. 8:57-2.12(c)2 the Department proposes an amendment to remove discussion about those who fail to report and replace it with clinical laboratory director.

N.J.A.C. 8:57-3 Reportable Occupational and Environmental Diseases, Injuries and Poisons

As previously discussed, the Department proposes to recodify N.J.A.C. 8:57-3 into its own chapter at N.J.A.C. 8:58, because occupational and environmental diseases, injuries, and poisonings are markedly different in scope, source, and preventability than communicable diseases. The Department proposes to reserve subchapter 3 for future use. The Department will discuss proposed recodified N.J.A.C. 8:58 further in the Summary.

N.J.A.C. 8:57-4: Immunization of Pupils in School

The Department proposes to readopt N.J.A.C. 8:57-4 and proposes the amendments discussed below. N.J.A.C. 8:57-4 has and would continue to

establish a set of uniform immunization requirements applicable to children attending all schools, preschools, and child care facilities in New Jersey. The Department's objectives in establishing rules as a condition for children entering or attending school continue to be as follows:

1) To ensure that all children attending school have been immunized against specific vaccine preventable diseases with recommended vaccines;

2) To prevent the transmission of vaccine preventable diseases by maintaining high immunization rates in school aged and preschool aged children; and

3) To collect data on the immunization status of children attending schools, preschools, and child care facilities in order to identify areas of the State where immunization rates are not adequate so that intervention measures can be instituted.

The United States Food and Drug Administration (FDA) has licensed all vaccines currently mandated by N.J.A.C. 8:57-4. The Advisory Committee on Immunization Practices (ACIP) of the Centers for Disease Control and Prevention (CDC) of the United States Department of Health and Human Services has recommended the use of the vaccines currently mandated by N.J.A.C. 8:57-4. The American Academy of Pediatrics (AAP), the American Academy of Family Physicians (AAFP), and the Public Health Council also endorse the use of these vaccines. The Department follows the periodically revised recommendations of the ACIP for the routine administration of each communicable disease vaccine to

the pediatric population, as applicable to New Jersey. The Department continues to follow the annual "Recommended Childhood and Adolescent Immunization Schedule" and the annual "Recommended Immunization Schedule For Children and Adolescents Who Start Late or Who Are More Than 1 Month Behind" as approved by the ACIP, the AAP and the AAFP, regarding the appropriate periodicity, dosage, and contraindications applicable to the vaccines. The recommendations for each communicable disease and the recommended immunization schedules are available for download through the ACIP website at http://www.cdc.gov/nip/ACIP/default.htm. Paper copies of the various ACIP recommendations and immunization schedules as published in the Morbidity and Mortality Monthly Report by the CDC are available by subscription through the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402; telephone (202) 512-1800.

The rules proposed for readoption at N.J.A.C. 8:57-4 have and would continue to set forth the applicability of the subchapter and the prohibition against any school, preschool or child care facility from admitting or retaining any child that does not have acceptable evidence of immunizations required by this subchapter except for those that have permitted exemptions (4.1 and 4.2). The rules proposed for readoption at N.J.A.C. 8:57-4 have and would continue to set forth criteria for obtaining a medical or religious exemption to the immunizations required pursuant to this subchapter (4.3 and 4.4). The rules proposed for

readoption at N.J.A.C. 8:57-4.5 would continue to establish the criteria for when provisional admission to a school, preschool, or child care center is required.

The rules proposed for readoption at N.J.A.C. 8:57-4 have and would continue to establish the documents acceptable as proof of immunization (4.6); the requirement for schools, preschools, and child care centers to retain immunization record for every pupil and retain them separately from educational records (4.7); and the method and timing for schools, preschools, and child care centers to submit an annual immunization status report to the Department (4.8). The rules proposed for readoption at N.J.A.C. 8:57-4.9 would continue to set forth the requirement that schools, preschools, and child care centers make immunization records for their pupils available to authorized representatives of the Department or local board of health with jurisdiction for inspection (4.9).

The rules proposed for readoption at N.J.A.C. 8:57-4 would continue to set forth the age and/or grade and dose timing requirements for the following vaccines which are required for entry and attendance in New Jersey schools, preschools, and child care centers: Diptheria and tetanus toxoids and pertussis (4.10); Poliovirus (4.11); Measles virus (4.12); Rubella (4.13); Mumps (4.14); Haemophilus influenzae type b (Hib) conjugate (4.15); and Hepatitis B virus (4.16); and Varicella virus (4.17). The Department proposes to readopt rules at N.J.A.C. 8:57-4 that were recently adopted (See 38 N.J.R. 5284(a) and 40 N.J.R. 151(a)) but which are not operative until September 1, 2008. Some of those readopted rules also set forth the age and/or grade and dose timing requirements

for the following vaccines which are required for entry and attendance in New Jersey schools, preschools, and child care centers: Tdap at 4.10(h) through (j); Pneumococcal conjugate (4.18); Influenza (4.19); and Meningococcal (4.20).

The rules proposed for readoption at N.J.A.C. 8:57-4.21 would continue to set forth that a board of education and/or local board of health may provide at public expense the necessary equipment, materials, and services for specified immunizing agents. The rules proposed for readoption at N.J.A.C. 8:57-4.22 would continue to articulate the emergency powers of the Commissioner with regard to public health immunization emergencies. The rules proposed for readoption at N.J.A.C. 8:57-4.23 would continue to set forth the Department's optimal immunization recommendation and the requirement that any doses of vaccine administered pursuant to this subchapter that are less than or equal to four days before either the specified minimum age or dose spacing interval are valid and do not require revaccination. The Department proposes to readopt N.J.A.C. 8:57-4.24, which was recently adopted (See 38 N.J.R. 5284(a) and 40 N.J.R. 151(a)) but which is not operative until September 1, 2008 and which articulates in this subchapter the penalty for violations of this subchapter.

The Department also proposes to readopt the following sections of N.J.A.C. 8:57-4 as discussed above, where the Department recently adopted amendments that are not operative until September 1, 2008, (See 38 N.J.R. 5284(a) and 40 N.J.R. 151(a)): 4.5, 4.7, 4.8, 4.11, 4.12, 4.15, 4.16, 4.21, and 4.22.

The Department proposes an amendment at N.J.A.C. 8:57-4.6 to add a subsection that sets forth laboratory evidence of protective immunity, as enumerated by the ACIP, as another means by which a parent or guardian can provide evidence of a child's immunizations as required by this subchapter for admission to a school, preschool, or child care facility. Consequently, the Department proposes amendments at N.J.A.C. 8:57-4.12(e), 4.13(c), and 4.14(d) to remove duplicative language from those sections. The Department also proposes amendments at N.J.A.C. 8:57-4.18(a) and (b). N.J.A.C. 8:57-4.18(a) establishes the pneumococcal conjugate vaccine (PCV) requirement applicable to all children two through 11 months of age who are attending a licensed child care center or preschool facility on or after September 1, 2008. The Department proposes an amendment to remove the term "preschool facility" because children two through 11 months of age would not enroll in or attend a preschool facility. N.J.A.C. 8:57-4.18(b) requires that all children 12 through 59 months of age who are attending a licensed child care center on or after September 1, 2008 shall have received at least one dose of PCV vaccine on or after their first birthday. The Department proposes an amendment to add the term "preschool facility" at N.J.A.C. 8:57-4.18(b) because children who are in the 12 through 59 months of age bracket could enroll in or attend a preschool facility. In the last rulemaking applicable to N.J.A.C. 8:57-4.18, the Department inadvertently added preschool facilities to the incorrect subsection and now proposes amendments to correct that mistake.

N.J.A.C. 8:57-5: Confinement of Persons With Tuberculosis

The rules proposed for readoption at N.J.A.C. 8:57-5 have and would continue to establish the purpose and scope of this subchapter; definitions of words and terms used throughout the subchapter; the grounds for commitment of a patient with tuberculosis; due process rights due to a person at any hearing conducted pursuant to this subchapter; the requirement that the manager of the Department's tuberculosis (TB) program complete an annual report describing trends on TB in this State; the confidentiality of information submitted to the Department pursuant to this subchapter; and articulate the applicable penalties for violation of this subchapter.

The Department proposes amendments throughout N.J.A.C. 8:57-5 to make grammatical, technical, and formatting changes in order to better articulate the requirements of the rules and make changes to utilize new definitions. The Department also proposes substantive amendments, repeals, and new rules and as a result, there are proposed recodifications.

The Department proposes to repeal the following existing sections of N.J.A.C. 8:57-5 because these sections are outdated and the Department is proposing updated and more applicable content that would provide better guidance to the regulated community as proposed new rules: "Reportable events (5.3)," "Case management and outreach services (5.4)," "Diagnostic examinations (5.5)," "Management of TB; outpatient basis (5.6)," "Hearing process (5.8),"

"Discharge plan (5.10)," "Commitment facilities (5.11)," "Procedures for commitment by local health officers (5.12)," "Mandatory exclusion from workplace or school (5.15)," and "Penalties (5.16)."

The Department proposes an amendment at N.J.A.C. 8:57-5 to change the name of the subchapter to the following: "Management of Tuberculosis" in order to more accurately reflect the content of this subchapter in its revised form. The Department proposes revisions to the language and content of this subchapter to: conform to the prescribed format, expand the scope of the rules to better monitor the quality and promote the continuity of care provided to patients with TB, identify and ensure reporting of TB transmission in the community, protect the public against avoidable TB transmission, promote the completion of treatment, and provide increased clarity to the process to correct patient non-adherence with diagnostic evaluation, infection control measures and prescribed treatment in the least restrictive manner possible.

The Department proposes an amendment at N.J.A.C. 8:57-5.1 to better articulate the purpose and scope of the subchapter and state the persons that have the responsibility to implement N.J.A.C. 8:57-5.

The Department proposes a new rule at N.J.A.C. 8:57-5.2 to set forth, in one central location, the documents that the Department is incorporating by reference in this subchapter. The Department proposes to incorporate by reference, as amended and supplemented, Morbidity and Mortality Weekly Report (MMWR), Treatment of Tuberculosis, published by the Centers for

Disease Control and Prevention on June 20, 2003, volume 52, number RR-11, (hereinafter MMWR, Treatment of Tuberculosis). The Department proposes to incorporate by reference the following forms in this subchapter: TB-70: Tuberculosis Case, Suspect and Status Report, which is the form for reporting suspected or confirmed TB disease and updating the status of these patients and is available at proposed subchapter 5 Appendix A; and TB-41: Record of Contact Interview, which is the form for reporting the identification, results of medical evaluation and final disposition of contacts and is available at proposed subchapter 5 Appendix B.

The Department proposes to recodify existing N.J.A.C. 8:57-5.2 as N.J.A.C. 8:57-5.3. The Department proposes amendments to add the following new definitions at recodified N.J.A.C. 8:57-5.3: "Administrator," "Class B1 or B2 referrals," "contact," "extensively drug resistant tuberculosis (XDR-TB)," "field services," "hospital," "immediate or imminent public health risk," "index case," "infection control measures," "interferon gamma release assay," "nucleic acid amplification test," "Public Health Nurse Case Manager," "public health warning notice," "risk for flight," "source case investigation," "suspected or confirmed infectious or potentially infectious TB disease," "suspected or confirmed TB disease," and "vulnerable population." The Department proposes amendments to revise the following definitions at recodified N.J.A.C. 8:57-5.3 in order to clarify these words and terms: "Acid fast bacilli (AFB)," "directly observed therapy (DOT)," "health care provider," "health officer order," "Latent TB

infection," "least restrictive environment or manner," and "Multiple drug resistant tuberculosis (MDR-TB)." The Department proposes amendments to delete the following definitions at recodified N.J.A.C. 8:57-5.3 because these words and terms are no longer used in the subchapter or are defined at proposed N.J.A.C. 8:57-1.3, which is proposed to be applicable to the entire chapter: "active TB," "appointment keeping rate," "clinically suspected active TB," "close contact," "Commissioner," "compliance," "designated commitment facility or unit," "infectious tuberculosis," "local health officer," "loss of contact," "Manager, TB Program," "medical director," "restraining order," "social resources," "TB control agency," and "warning notice."

The Department proposes to add a new rule at N.J.A.C. 8:57-5.4. Proposed new N.J.A.C. 8:57-5.4 would establish the persons required to report suspected or confirmed TB disease to the Department and the methods, timeframe and circumstances for reporting. Proposed new N.J.A.C. 8:57-5.4 would set forth the TB-70 form available in proposed subchapter 5 Appendix A as the required form for reporting persons with suspected or confirmed TB disease. Proposed new N.J.A.C. 8:57-5.4 would establish that for patients managed by public health clinics, these reporting requirements would be the responsibility of the public health nurse case manager in the patient's jurisdiction of residence.

Proposed new N.J.A.C. 8:57-5.4 would establish the methods, timeframe and circumstances where public health nurse case managers in the index case's jurisdiction of residence would be required to submit a TB-41 form, available at

proposed subchapter 5 Appendix B, to the Department's TB Program. Proposed new N.J.A.C. 8:57-5.4 would set forth that the Department's TB Program will inform and secure evaluation results and final disposition for identified contacts from health jurisdictions outside New Jersey. Proposed new N.J.A.C. 8:57-5.4 would set forth that health care providers would be required to report information on the evaluation results and final disposition of identified contacts to public health nurse case managers upon request.

Proposed new N.J.A.C. 8:57-5.4 would establish that health care providers that do not work for a public health clinic would be required to report verbally to the Department's TB Program or local designee whenever any patient with suspected or confirmed infectious or potentially infectious TB disease misses two consecutive appointments for medical assessment.

Proposed new N.J.A.C. 8:57-5.4 would establish that administrators of hospitals would be required to report to the Department's TB Program within 24 hours whenever an inpatient with suspected or confirmed infectious or potentially infectious TB disease poses an immediate or imminent public health risk.

Proposed new N.J.A.C. 8:57-5.4 would establish that administrators of hospitals would be required to report to the Department's TB Program the proposed discharge date for all patients with suspected or confirmed infectious or potentially infectious TB disease on the last business day that is at least 48 hours prior to the discharge date and if this requirement cannot be met, then the discharge must be delayed.

Proposed new N.J.A.C. 8:57-5.4 would establish that administrators of correctional facilities must report to the Department's TB Program the release of an inmate with suspected or confirmed infectious or potentially infectious TB disease either, two working days prior to release if the date is known in advance or within one working day after release if the release was not anticipated.

The Department proposes a new rule at N.J.A.C. 8:57-5.5, which would establish the criteria that health care providers must use to determine when to discharge an inpatient with suspected or confirmed infectious or potentially infectious TB, in order to protect the community against avoidable transmission. The proposed rules at new N.J.A.C. 8:57-5.5 would be liberal for inpatients with a stable private residence, without members of a vulnerable population as co-residents, but more stringent for inpatients that are homeless, have an unstable residence, share a residence with members of a vulnerable population group, or live in a congregate setting, due to a higher risk of transmission. The proposed rules at new N.J.A.C. 8:57-5.5 would articulate the Department's authority to investigate a hospital's discharge of a patient that does not meet one of the criteria for discharge and impose a penalty, when applicable, for a licensure violation as identified by the Department's Division of Health Facilities Evaluation and Licensure.

The Department proposes a new rule at N.J.A.C. 8:57-5.6, which would articulate the responsibilities of health officers, which include: the provision of a health care provider, public health nurse case management services, and field

services for residents in the health jurisdiction with suspected or confirmed TB disease and latent TB infection. Proposed new N.J.A.C. 8:57-5.6 would require a health care provider providing medical management and treatment to residents of New Jersey with suspected or confirmed TB disease or latent TB infection to use the Morbidity and Mortality Weekly Report (MMWR), Treatment of Tuberculosis, incorporated by reference, as amended and supplemented. Proposed new N.J.A.C. 8:57-5.6 would also establish the Department's TB Program responsibility to provide verbal translation services to public health clinics, public health nurse case managers, and field staff serving patients with suspected or confirmed TB disease and/or latent TB infection.

The Department proposes a new rule at N.J.A.C. 8:57-5.7, which would require the public health nurse case manager in the patient's jurisdiction of residence or the public health nurse case manager in the jurisdiction where a hospital is located, or his or her designee, to provide each patient with suspected or confirmed infectious or potentially infectious TB with notification of infection control measures that are essential to protect the public against transmission. Proposed new N.J.A.C. 8:57-5.7 would require the public health nurse case manager to provide this notification both verbally and in writing within three working days of notification of the patient's disease status or receipt of a TB-70 form, whichever comes first. Proposed new N.J.A.C. 8:57-5.7 would require the public health nurse case manager or designee to notify the patient within one working day when the infection control measures established at proposed section

5.7 are no longer required. Proposed new N.J.A.C. 8:57-5.7 would establish the criteria to determine when the infection control measures are no longer required. Proposed new N.J.A.C. 8:57-5.7 would require that a health officer or designee issue a health officer order for isolation or health officer order for temporary commitment, as appropriate pursuant to proposed new sections 5.11 and 5.12, if the patient does not comply with infection control measures, which would be stated in the notification.

The Department proposes a new rule at N.J.A.C. 8:57-5.8 to establish the requirements for diagnostic evaluations. Proposed new N.J.A.C. 8:57-5.8 would require the public health nurse case manager to monitor and facilitate the timely diagnostic evaluation of all patients with suspected or confirmed infectious TB disease, their contacts and Class B1 or B2 referrals regardless of the type of health care provider. Proposed new N.J.A.C. 8:57-5.8 would establish the timeframes for a timely diagnostic evaluation in various circumstances. Proposed new N.J.A.C. 8:57-5.8 would establish the minimum components of a diagnostic evaluation for a person with suspected or confirmed infectious or potentially infectious TB disease, contacts to those persons, and Class B1 or B2 referrals.

The Department proposes a new rule at N.J.A.C. 8:57-5.9, which would set forth the persons responsible and methods for ordering and providing directly observed therapy (DOT). Proposed new N.J.A.C. 8:57-5.9 would establish that the order for DOT would be the responsibility of the health care provider and the provision of DOT for the duration of the order would be the responsibility of the

health officer. Proposed new N.J.A.C. 8:57-5.9 would establish that the negotiation of a time and place for DOT is the responsibility of the public health nurse case manager. Under proposed new N.J.A.C. 8:57-5.9 the public health nurse case manager would also be responsible for monitoring the patient's adherence to DOT and intervening whenever this adherence falls below 80 percent of prescribed doses over any one month period while treatment is ongoing.

The Department proposes a new rule at N.J.A.C. 8:57-5.10, which would set forth the responsibilities and methods of managing non-adherent patients that require a diagnostic evaluation or DOT. Under proposed new N.J.A.C. 8:57-5.10, if a patient with suspected or confirmed infectious or potentially infectious TB disease either refuses DOT as ordered by a health care provider or is less than 80 percent adherent to a prescribed DOT treatment regimen over any one month period, the public health nurse case manager would be responsible for the initiation of interventions to correct the adherence issue. Under proposed new N.J.A.C. 8:57-5.10, the first step in this process would be a public health warning notice issued by the public health nurse case manager. This warning notice, pursuant to proposed new N.J.A.C. 8:57-5.10, would require the patient to adhere to the prescribed DOT treatment regimen. Under proposed new N.J.A.C. 8:57-5.10, if the patient continues to refuse DOT or remains less than 80 percent adherent with a prescribed DOT treatment regimen, then the health officer in the patient's jurisdiction of residence or jurisdiction where the patient is located

would be required to issue a health officer order for DOT. Proposed new N.J.A.C. 8:57-5.10 would establish the acceptable methods for serving the public health warning notice and/or health officer order for DOT. Under proposed new N.J.A.C. 8:57-5.10, if refusal or non-adherence persists, the health officer may petition the Superior Court for court ordered DOT after seeking consultation with the Department's TB Program or the State Epidemiologist. Proposed new N.J.A.C. 8:57-5.10 would establish that any public health warning notice, health officer order or court order for DOT issued under this process would remain in effect until the health care provider no longer prescribes DOT or treatment is complete, whichever occurs first. For this reason, under proposed new N.J.A.C. 8:57-5.10, if non-adherence recurs during the patient's course of treatment, the process would begin with the next step in the process depending on where the process ended initially.

Proposed new N.J.A.C. 8:57-5.10 would establish the process for intervention if a patient with suspected or confirmed infectious or potentially infectious TB disease, an identified contact to such a patient or Class B1 or B2 referral refuses to report for a diagnostic evaluation or misses two consecutive appointments for a diagnostic evaluation to determine his or her TB status. The process proposed at new N.J.A.C. 8:57-5.10 would begin with a public health warning notice for diagnostic evaluation issued by the public health nurse case manager and the proposed new rule would establish the contents of the warning notice. Under proposed new N.J.A.C. 8:57-5.10 if the patient does not contact the

public health nurse case manager or clinic to schedule an appointment within three days of receipt of the notice, the health officer in the jurisdiction of residence or jurisdiction where the patient is located must issue a health officer order for diagnostic evaluation. Proposed new N.J.A.C. 8:57-5.10 would establish the acceptable methods for serving the health officer order for diagnostic evaluation. Under proposed new N.J.A.C. 8:57-5.10 if the patient does not contact the public health nurse case manager within three business days to schedule an appointment for diagnostic evaluation, the health officer may petition the Superior Court for court ordered diagnostic evaluation after seeking consultation with the Department's TB Program or the State Epidemiologist. Under proposed new N.J.A.C. 8:57-5.10 the public health warning notice, health officer order or court order for diagnostic evaluation is in force only until the requirement for diagnostic evaluation is satisfied. If non-adherence recurs during the patient's course of treatment, under proposed new N.J.A.C. 8:57-5.10, the process would begin again with a health officer order.

The Department proposes a new rule at N.J.A.C. 8:57-5.11, which would set forth the responsibilities and methods of managing non-adherent patients through a health officer order for isolation. Under proposed new N.J.A.C. 8:57-5.11, the health officer in the patient's jurisdiction of residence or jurisdiction where the patient is located may issue a health officer order for isolation restricting the patient from a workplace, school or other premises if a patient is determined to be an immediate or imminent risk to the public health after

consultation with the Department's TB Program or State Epidemiologist. Proposed new N.J.A.C. 8:57-5.11 would set forth the timeframe for issuing and the maximum effective duration of the health officer order for isolation. Under proposed new N.J.A.C. 8:57-5.11, if the patient requests a court review of a health officer order for isolation, the health officer would be required to petition the Superior Court for review of such order within five business days of the request and the health officer order for isolation would not continue for more than 10 business days without a court order continuing isolation. Proposed new N.J.A.C. 8:57-5.11 would establish the acceptable methods for delivering a health officer order for isolation to the patient. Proposed new N.J.A.C. 8:57-5.11 would set forth that if the patient violates the health officer order, the health officer may petition the Superior Court for a for a hearing, seeking court ordered commitment after consultation with the Department's TB Program or State Epidemiologist. Proposed new N.J.A.C. 8:57-5.11 would articulate the Commissioner's or designee's responsibility to designate the commitment venue if it is determined appropriate to petition the court for commitment, in consultation with the health officer and the TB Program. Proposed new N.J.A.C. 8:57-5.11 would establish parameters for the place of commitment.

The Department proposes a new rule at N.J.A.C. 8:57-5.12, which would set forth the responsibilities and methods of managing non-adherent patients through a health officer order for temporary commitment. Under proposed new N.J.A.C. 8:57-5.12, if the Commissioner, State Epidemiologist or designee or the

health officer in the patient's health jurisdiction determines that the patient is not only an immediate or imminent risk to the public health, but also a risk for flight, the health officer would be required to order the patient to temporary commitment. Proposed new N.J.A.C. 8:57-5.12 would establish the means for determining appropriateness of temporary commitment and a location for commitment; the timeframe for issuing and the maximum effective duration of the order for temporary commitment; the information that would be provided to local law enforcement as applicable under the proposed rules; and the requirement for an expedited commitment hearing in Superior Court. Under proposed new N.J.A.C. 8:57-5.12 the health officer that issued the order for temporary commitment would be required to seek the assistance of local legal counsel to prepare the petition for commitment for submission to the Superior Court.

The Department proposes to recodify existing N.J.A.C. 8:57-5.7 as N.J.A.C. 8:57-5.13. The Department proposes to make technical amendments at recodified N.J.A.C. 8:57-5.13(a), and substantive amendments that would remove the language covering when the Superior Court must be petitioned for commitment in order to replace that language with the cross citations for proposed new sections that set forth those circumstances. The Department proposes an amendment at recodified N.J.A.C. 8:57-5.13(b) to add new language establishing that the issuance of a health officer order for temporary commitment would require an expedited review by the Superior Court. The Department proposes to

recodify existing N.J.A.C. 8:57-5.7(b) as N.J.A.C. 8:57-5.13(c) and to make grammatical revisions at recodified N.J.A.C. 8:57-5.13(c).

The Department proposes a new rule at N.J.A.C. 8:57-5.14, which would establish that the health officer, Commissioner, State Epidemiologist or a designee would be required to put a patient to be committed on notice of his or her right to a hearing in Superior Court. Proposed new N.J.A.C. 8:57-5.14 would set forth the required contents of such notice, place of commitment, timeframe for seeking renewed court review, and circumstances for seeking an order to rescind a court order for commitment. Proposed new N.J.A.C. 8:57-5.14 would also set forth the requirement for the health officer, Commissioner, State Epidemiologist or designee to inform Superior Court of any violation of a court order for commitment.

The Department proposes to recodify N.J.A.C. 8:57-5.9 as N.J.A.C. 8:57-5.15 and to readopt that section, which covers due process rights, without any changes.

The Department proposes to recodify N.J.A.C. 8:57-5.13 as N.J.A.C. 8:57-5.16. The Department proposes an amendment at recodified N.J.A.C. 8:57-5.16 to clarify that the Department's required report would be made available to the public and to remove text that is no longer applicable or that is duplicative of existing text.

The Department proposes to recodify N.J.A.C. 8:57-5.14 as N.J.A.C. 8:57-5.17. The Department proposes an amendment at recodified N.J.A.C. 8:57-

5.17(b) to remove the existing language and to add language to articulate that the reports and forms submitted to the Department pursuant to subchapter 5 are not government records subject to public access or inspection within the meaning of N.J.S.A. 47:1A-1 et seq.

The Department proposes to recodify N.J.A.C. 8:57-5.16 as N.J.A.C. 8:57-5.18. The Department proposes an amendment at recodified N.J.A.C. 8:57-5.18 to remove existing text and replace that text with more clear and specific circumstances under which penalties may be issued due to violation of any of the rules under subchapter 5.

N.J.A.C. 8:57-6: Higher Education Immunization

The Department proposes to readopt with amendments and new rules N.J.A.C. 8:57-6. The rules proposed for readoption at N.J.A.C. 8:57-6 would continue to establish a set of uniform immunization requirements applicable to specified students entering or attending institutions of higher education. P.L. 1988, c.158 (N.J.S.A. 18A:61D-1 et seq.) and rules promulgated thereunder at N.J.A.C. 9:2-14 (Expired as of May 4, 1995; rules of the former Department of Higher Education) required all undergraduate and graduate students born after 1957 and enrolled in a program leading to an academic degree, to submit proof of immunization as a condition of admission or continued enrollment. On July 12, 1994, the Higher Education Restructuring Act of 1994 abolished the Department of Higher Education (P.L. 1994, c.48). This act also amended the aforementioned

statute and transferred the Department of Higher Education's authority to regulate student immunization to this Department. The Department is proposing amendments and new rules at N.J.A.C. 8:57-6 primarily to implement a new hepatitis B immunization rule to become operative by September 2008 as mandated by N.J.S.A. 18A:61D-9 and is also proposing other substantive amendments to this subchapter.

The rules proposed for readoption have established and would continue to establish the applicability of this subchapter; acceptable exemptions and qualifications for those exemptions; the immunizations required for entry and attendance in a New Jersey institution of higher education, as specified in this subchapter; the institutional responsibility for enforcement of this subchapter; standards for provisional admission; acceptable documents as evidence of immunization; records required to be maintained by institutions; the requirements that institutions make immunization records available to authorized representatives of the Department or the local board of health with jurisdiction; the institution's ability to administer required vaccines; reporting requirements; and the Commissioner's or local health officer's authority to make modifications to required vaccines in the event of an outbreak or shortage.

The Department proposes amendments throughout subchapter 6 to replace the terms "'colleges,' 'universities,' and 'colleges and universities'" with the terms "'institution of higher education' or 'institution'" for clarity and consistency of language. The Department proposes amendments at N.J.A.C. 8:57-6.1 to

change the section title from “Applicability” to “Purpose and scope” to be consistent with current Department rulemaking procedure and to add a new subsection to more clearly articulate the purpose of this subchapter. As a result, the Department proposes to recodify the existing subsections accordingly. The Department proposes amendments at N.J.A.C. 8:57-6.1 to cite the appropriate sections that establish the exception to application of this subchapter as specified for the hepatitis B vaccine as applicable for four-year institutions. The Department proposes amendments at N.J.A.C. 8:57-6.1 to cite to the appropriate recodified sections that cover the meningococcal rule.

The Department proposes a new rule at new N.J.A.C. 8:57-6.2 to set forth, in one central location, the documents that the Department is incorporating in this subchapter. The Department proposes to incorporate by reference in this subchapter the Annual College Immunization Status Report form (IMM-3), available in the subchapter Appendix, which each institution shall use to provide a report of students’ immunization status to the Department on an annual basis.

The Department proposes a new rule at new N.J.A.C. 8:57-6.3 to establish definitions of the following words and terms as used in this subchapter: “ACIP,” “advanced practice nurse,” “campus dormitory,” “institution of higher education or institution,” “minor,” “NJIIS,” and “New Jersey Vaccine Preventable Disease Program.”

The Department proposes to recodify existing N.J.A.C. 8:57-6.2 as N.J.A.C. 8:57-6.4. The Department proposes amendments at recodified N.J.A.C.

8:57-6.4(a) to provide correct citations to recodified sections. The Department proposes minor grammatical amendments at recodified N.J.A.C. 8:57-6.4(b) to change the language used from the passive voice to the active voice. The Department proposes an amendment at recodified N.J.A.C. 8:57-6.4(b)2 to clarify that matriculated students attending class in off-campus facilities or locations are to comply with the subchapter in the same manner as if those classes were held at an on-campus location.

The Department proposes an amendment at recodified N.J.A.C. 8:57-6.4(c) to delete the words "Advisory Committee on Immunization Practices (ACIP) of the United States Public Health Service" and replace them with ACIP, which would be a defined term. The Department proposes to recodify existing N.J.A.C. 8:57-6.3 as N.J.A.C. 8:57-6.5. The Department proposes to amend recodified N.J.A.C. 8:57-6.5(a) to separate the existing subsection into two separate statements by adding a paragraph at 6.5(a)1 without making a substantive change in meaning, to better organize this subsection for the reader.

The Department proposes to amend recodified N.J.A.C. 8:57-6.5(c) to establish that laboratory serologic proof of immunity in lieu of receiving a measles containing vaccine in order to meet either the first or second dose measles vaccine requirement is an acceptable alternative to measles vaccine receipt. This alternative has been a part of these rules for many years, but with the passage of N.J.S.A. 26:2N-8 through 11, (Holly's Law) in 2004, the Department believes it is prudent to more explicitly state this option for those

students who need to satisfy the requirement of a second measles containing vaccine dose.

The Department also proposes an amendment to add a new subsection at N.J.A.C. 8:57-6.5(d) to establish that a measles virus containing vaccine administered up to four days before either the student's first birthday or four days before the specified minimum dose spacing interval of one month, 28 days, shall be counted as a valid dose. This four-day grace period would not replace existing ACIP vaccine scheduling recommendations or the Federal Food and Drug Administration (FDA) vaccine licensure statements on the timing of vaccine doses. This proposed administrative action would be consistent with the national ACIP position permitting a four-day grace period, and would primarily be used by institution's health officials in their review, assessment, and audit of student immunization records.

The Department proposes to recodify existing N.J.A.C. 8:57-6.4 as N.J.A.C. 8:57-6.6. The Department proposes to amend recodified N.J.A.C. 8:57-6.6(a) to separate the existing subsection into two separate statements by adding a paragraph at 6.6(a)1 without making a substantive change in meaning, to better organize this subsection for the reader.

The Department proposes an amendment to add a new subsection at recodified N.J.A.C. 8:58-6.6(c) to establish that a mumps virus containing vaccine administered up to four days before the student's first birthday shall also be counted as a valid dose. While not changing their recommendation that all doses

of mumps containing vaccine be given on or after the first birthday, the ACIP announced in 2000 that vaccines administered up to four days before a specified recommended minimum age or interval would be counted as a valid dose.

The Department proposes to recodify existing N.J.A.C. 8:57-6.5 as N.J.A.C. 8:57-6.7. The Department proposes an amendment at recodified N.J.A.C. 8:57-6.7(a) to separate the existing subsection into two separate statements by adding a paragraph at 6.7(a)1 without making a substantive change in meaning, to better organize this subsection for the reader.

The Department proposes an amendment to add a new subsection at recodified N.J.A.C. 8:57-6.7(c) to establish that a dose of rubella containing vaccine administered up to four days before the first birthday shall also be counted as a valid dose. While not changing their recommendation that all doses of rubella vaccine be given on or after the first birthday, the ACIP announced in 2000 that vaccines administered up to four days before a specified recommended age or interval would be counted as a valid dose.

The Department proposes to recodify existing N.J.A.C. 8:57-6.6 as N.J.A.C. 8:57-6.8. The Department proposes an amendment at recodified N.J.A.C. 8:57-6.8(a) to correct existing citations to reflect recodified sections. The Department proposes an amendment at recodified N.J.A.C. 8:57-6.8(b) to add a new subsection to establish that a student would be exempt from the meningococcal vaccine requirement if the student objects thereto in a written statement submitted to the institution, signed by the student, explaining how the

administration of meningococcal vaccine conflicts with the bona fide religious tenets or practices of the student, except that a general philosophical or moral objection to the vaccination would not be sufficient for an exemption on religious grounds. The Department also proposes to supplement the statutory language to clarify that if a student is a minor, the parent or legal guardian must sign a religious exemption statement regarding the immunizations rules. The proposed religious exemption language for meningococcal vaccine is required by statute at N.J.S.A. 18A:62-15.2.

The Department proposes a new rule at new N.J.A.C 8:57-6.9 to establish that hepatitis B vaccine would be a required vaccine for certain students first entering an institution to become operative for certain new students first entering after September 1, 2008. Since high school students have been required under N.J.A.C. 8:57-4.16 to receive hepatitis B vaccine, the Department, here in subchapter 6, proposes similar language to that rule affecting high school students, wherever possible, for reasons of uniformity, administrative familiarity, ease of implementation, and for consistent enforcement. The statute mandates hepatitis B vaccine for those students first enrolling in an academic degree program at a two or four-year institution with 12 or more hours of course study per semester or term. At proposed new N.J.A.C. 8:57-6.9(a) students would be required to document receipt of either three doses of a hepatitis B containing vaccine or alternatively the special two dose hepatitis B vaccine formulation only given between 11 through 15 years of age. At proposed new N.J.A.C. 8:57-

6.9(b) students not immunized would be permitted up to nine months to complete the three dose hepatitis B vaccine series. The proposed language at N.J.A.C. 8:57-6.9(b) would grant a provisional status of nine months for hepatitis B vaccine and is required by statute at N.J.S.A. 18A:61D-9(a). The Department proposes two new subsections at N.J.A.C. 8:57-6.9(c) and (d) to establish that there is a medically recommended time period for incompletely vaccinated persons to complete the three doses hepatitis B vaccine series. Students with one or two documented dose of hepatitis B vaccine would not need an entire nine months to complete this three dose vaccine series. The shorter time periods proposed by the Department are consistent with the current ACIP Recommended Adult Immunization Schedule, which is available for download through the CDC website at http://www.cdc.gov/nip/ACIP/default.htm. At proposed new N.J.A.C. 8:57-6.9(c) a student entering with one documented dose of hepatitis B vaccine would be permitted up to six months to complete the hepatitis B vaccine series. At proposed new N.J.A.C. 8:57-6.9(d) a student entering with two documented doses of hepatitis B vaccine would be permitted no more than four months to complete the hepatitis B vaccine requirement. At proposed new N.J.A.C. 8:57-6.9(e) students would alternatively be permitted to provide documented laboratory evidence of past hepatitis B disease or immunity, constituting a medical exemption, in lieu of receiving hepatitis B vaccine. At proposed new N.J.A.C. 8:57-6.9(f) a student would be exempt from the hepatitis B vaccine requirement if the student objects thereto in a written statement submitted to the institution,

signed by the student, explaining how the administration of hepatitis B vaccine conflicts with the bona fide religious tenets or practices of the student, except that a general philosophical or moral objection to the vaccination would not be sufficient for an exemption on religious grounds. The proposed religious exemption language for hepatitis B vaccine is required by statute at N.J.S.A. 18A:61D-10(b). The Department also proposes to supplement the statutory language to clarify that if student is a minor, the parent or legal guardian must sign a religious exemption statement regarding the immunization rules.

The Department proposes to recodify existing N.J.A.C. 8:57-6.7 as N.J.A.C. 8:57-6.10. The Department proposes to amend recodified N.J.A.C. 8:57-6.10(c) to update the appropriate references in this subsection necessary because of recodification.

The Department proposes to recodify existing N.J.A.C. 8:57-6.8 as N.J.A.C. 8:57-6.11. The Department proposes amendments at recodified N.J.A.C. 8:57-6.11(a) to update the appropriate references in this subsection necessary because of proposed recodifications in this subchapter.

The Department proposes to recodify existing N.J.A.C. 8:57-6.9 as N.J.A.C. 8:57-6.12. The Department proposes to amend recodified N.J.A.C. 8:57-6.12(a) to restate the existing language in the preferred active voice rather than the passive voice, without making any substantive change in meaning.

The Department proposes to amend recodified N.J.A.C. 8:57-6.12(b) to establish a statutorily declared exception that for the hepatitis B vaccine

requirement only, the provisional period shall extend beyond the existing first semester or term limit for the other required vaccines in this section. This proposed amendment at recodified N.J.A.C. 8:57-6.9(b) and (c) would enable an unvaccinated student to remain in provisional status for a period from four to nine months while remaining in college attendance to complete the three dose hepatitis B vaccine series.

The Department proposes to amend recodified N.J.A.C. 8:57-6.12(c) to articulate that an institution has the authority to temporarily exclude a student in provisional status from attending class or other institution-sponsored events when a certain vaccine preventable disease outbreak exists or threatens. The Department also proposes an amendment at recodified N.J.A.C. 8:57-6.12(c) to change passive voice to active voice. The Department is proposing to separate the existing subsection into two separate sentences by adding a paragraph at recodified N.J.A.C. 8:57-6.12(c)1 without making a substantive change in meaning in order to achieve better organization for the reader.

The Department proposes to recodify existing N.J.A.C. 8:57-6.10 as N.J.A.C. 8:57-6.13. The Department proposes to amend recodified N.J.A.C. 8:57-6.13(a) to restate the existing language in the preferred active voice rather than the passive voice, without effecting any substantive change in meaning. The Department proposes to amend recodified N.J.A.C. 8:57-6.13(a)1, 2, and 3 to add hepatitis B vaccine to the list of the previously mandated measles, mumps, rubella, and meningococcal vaccines for which college students must submit

documentation to prove compliance with the higher education immunization rules. The Department proposes to add a new paragraph at recodified N.J.A.C. 8:57-6.13(a)4 to establish that immunization records obtained from the New Jersey Immunization Information System (NJIIS) would also be an acceptable format available to assess and establish a student's compliance with N.J.A.C. 8:57-6. The development, implementation, and utilization of electronic state operated immunization record systems are nationally recommended. Since March 2005, the use of such records from the NJIIS is permitted by the Statewide Immunization Registry Act at N.J.S.A. 26:4-134(e). The statute states that a paper or electronic record of the NJIIS immunization record shall be accepted as a valid immunization or preventive health screening record of a registrant for the purpose of meeting health screening documentation requirements for admission to a school, college, or licensed child care center. The Department proposes to add a new paragraph at recodified N.J.A.C. 8:57-6.13(a)5 to establish that a health or immunization record from the United States Armed Forces shall be acceptable documentation for assessing student compliance with this subchapter.

The Department proposes to recodify existing N.J.A.C. 8:57-6.11 as N.J.A.C. 8:57-6.14. The Department proposes to amend recodified N.J.A.C. 8:57-6.14(a) to correct a previous typographical error to the word, "immunization(s)." The Department proposes to amend recodified N.J.A.C. 8:57-6.14(b) to delete the reference to "the most recent recommendations of the Advisory Committee on Immunization Practices" and instead reference the 2007

Advisory Committee on Immunization Practices (ACIP), Recommended Childhood, Adolescent, and Adult Immunization Schedules and the ACIP Recommendations. The Department proposes to amend recodified N.J.A.C. 8:57-6.14(c) to separate that subsection into two paragraphs at N.J.A.C. 8:57-6.14(c)1 and (c)2 without effecting the meaning of the existing rule to better organize the subsection for the reader. The Department proposes to amend recodified N.J.A.C. 8:57-6.14(d) to separate that subsection by adding a paragraph at N.J.A.C. 8:57-6.14(d)1 without changing the substantive meaning of the existing rule, to better organize this subsection for the reader.

The Department proposes to recodify existing N.J.A.C. 8:57-6.12 as N.J.A.C. 8:57-6.15. The Department proposes to amend recodified N.J.A.C. 8:57-6.15(a) to adopt the statutory language to specify that a student's claim for a religious exemption for meningococcal vaccine at proposed recodified N.J.A.C. 8:57-6.8(b) and hepatitis B vaccine at proposed new N.J.A.C. 8:57-6.9(f) shall be based upon the respective language as mandated at N.J.S.A. 18A:62-15.2a(2) and N.J.S.A. 18A:61D-10b. For students claiming a religious exemption from the measles, mumps, and rubella vaccine requirements at proposed recodified N.J.A.C. 8:57-6.5, 6.6, and 6.7 respectively, the Department proposes to amend the existing language at proposed recodified N.J.A.C. 8:57-6.15(a) to establish that if student is a minor, the parent or legal guardian must sign a religious exemption statement regarding the immunization rules. The Department proposes amended language at recodified N.J.A.C. 8:57-6.15(a) through (c) to replace the

passive voice with the preferred active voice and to create a new paragraph at 6.15(c)1 without changing the meaning of the rules, to better organize this section for the reader.

The Department proposes to recodify existing N.J.A.C. 8:57-6.13 as N.J.S.A. 8:57-6.16. The Department proposes to amend recodified N.J.A.C. 8:57-6.16(a) to separate the existing subsection and add a new paragraph at N.J.A.C. 8:57-6.16(a)1 without changing the meaning of the existing rule, to better organize this subsection for the reader. The Department proposes similar amendments to add new paragraphs at recodified N.J.A.C. 8:57-6.16(b) and 6.16(e) without changing the meaning of the existing rules, to better organize this subsection for the reader.

The Department proposes to recodify existing N.J.A.C. 8:57-6.14 as N.J.A.C. 8:57-6.17. The Department proposes to amend recodified N.J.A.C. 8:57-6.17(a) to replace language with the passive voice with the preferred active voice without changing the meaning of this rule for the reader. The Department proposes to amend recodified N.J.A.C. 8:57-6.17(a)1 to permit the electronic submission of annual immunization status reports from institutions. The Department proposes to use the existing Annual College Immunization Status Report (IMM-3), available at the subchapter Appendix. Institutions without computer access can still use the postal service to submit the report to the Department.

The Department proposes an amendment to delete the subsection at recodified N.J.A.C. 8:57-6.17(b) and move and substantially amend that subsection at proposed new N.J.A.C. 8:57-6.2(a). The Department will no longer routinely mail or send a blank Annual College Immunization Status Report to institutions; however, for those facilities lacking computers or internet access the Department will mail a blank Annual College Immunization Status Report upon verbal or written request.

The Department proposes to recodify existing N.J.A.C. 8:57-6.14(c) as 8:57-6.17(b) and to establish that an institution is responsible for documenting and reporting to the Department on the status of its enrolled students and to add that reporting on the number of students in provisional status is also required in this report. The Department proposes amendments at recodified subsections N.J.A.C. 8:57-6.17(c) and (d) to replace the passive voice with the preferred active voice, without changing the meaning of these subsections for the reader.

The Department proposes an amendment at recodified N.J.A.C. 8:57-6.17(e) to establish and recognize that the meningococcal section is not its own report, but rather part of the Annual College Immunization Status Report that four year institutions are required to complete.

The Department proposes to recodify existing N.J.A.C. 8:57-6.15 as N.J.A.C. 8:57-6.18. The Department proposes to amend recodified N.J.A.C. 8:57-6.18(a) to separate this subsection by adding a paragraph at proposed

6.18(a)1 without changing the meaning of the existing rule, to better organize this subsection for the reader.

The Department proposes to recodify existing N.J.A.C. 8:57-6.16 as N.J.A.C. 8:57-6.19. The Department proposes to amend recodified N.J.A.C. 8:57-6.19(a) to add hepatitis B vaccine to list of the other required vaccines which an institution of higher education may administer to its students and delete the word "these" as superfluous. The Department also proposes to correct an editorial oversight in a previous amendment to this subsection by reinserting the word "rubella" into the sentence listing those vaccines, which may be administered by institutions to their students. The Department proposes to add a new subsection at recodified N.J.A.C. 8:57-6.19(c) to establish that two and four-year institutions shall be required to offer hepatitis B vaccine to students either through the institution's student health service or by a contractual agreement with a community health care provider, as statutorily mandated at N.J.S.A. 18A:61D-9(c).

The Department proposes to recodify existing N.J.A.C. 8:57-6.17 as N.J.A.C. 8:57-6.20. The Department proposes to amend this subsection to update the proposed recodification and references to N.J.A.C. 8:57-1.5 and N.J.A.C. 8:57-1.6 that are part of subchapter 1 entitled Reportable Communicable Diseases currently undergoing readoption with amendments as part of this rulemaking.

The Department proposes to recodify existing N.J.A.C. 8:57-6.18 as N.J.A.C. 8:57-6.21. The Department proposes a substantive amendment at

recodified N.J.A.C. 8:57-6.21 that would amend and establish the title of this section to recognize that vaccine shortages can upset implementation of this subchapter. The Department proposes to amend recodified N.J.A.C. 8:57-6.21 to separate this section by adding a subsection at N.J.A.C. 8:57-6.21(a) and three paragraphs at proposed 6.21(a)1 through (a)3 without changing the meaning of the existing rule, to better organize this subsection for the reader. The Department proposes to add a new subsection at N.J.A.C. 8:57-6.21(b) to establish a specified procedure for the Department to more expeditiously suspend or relax the vaccine mandates, when specific vaccine shortages occur. The Department believes this action is necessary since there was a severe meningococcal vaccine shortage in 2005 to 2006 that made it difficult for college students to comply with the meningococcal vaccine requirement and for institutions to enforce the rule without a formal means to allow a relaxation of the rule due to the vaccine supply issue.

N.J.A.C. 8:57-7: Student Health Insurance

The Department proposes to readopt N.J.A.C. 8:57-7 without any changes. The Department initially proposed the rules at N.J.A.C. 8:57-7 to implement the provisions of N.J.S.A. 18A:62-15, which requires full-time students at public and private institutions of higher education to maintain health insurance and requires all public and private institutions of higher education in this State to offer health insurance coverage on a group or individual basis for purchase by students required to maintain such coverage.

N.J.A.C. 8:57-7 has and would continue to set forth the purpose and scope of this subchapter (7.1); requirements for health insurance coverage (7.2); requirements for documentation of coverage (7.3); requirements that all public and private institutions of higher education make health insurance coverage available for purchase to their students who must maintain such coverage (7.4); and the requirement to make available to the Department evidence of compliance with this subchapter (7.5).

N.J.A.C. 8:57-8: Childhood Immunization Insurance Coverage

Although immunizations are the single most cost effective strategy to prevent disease and its attendant social and economic costs, national studies have revealed that 22 percent of preschool-aged children in New Jersey were not appropriately immunized for their age in 2006. Although the reasons for under-utilization of vaccines are complex, there is evidence that cost plays a substantial role. The Department proposes to readopt with amendments and a new rule N.J.A.C. 8:57-8. At the Federal and State levels, legislation has been enacted to provide expanded insurance coverage and to provide free immunization services to the poor and medically indigent. In New Jersey, P.L. 1995, c. 316 was enacted on January 5, 1996 and became effective April 4, 1996. The purpose of P.L. 1995, c. 316, in part, was to make childhood immunizations more accessible to insured children in New Jersey by mandating that health insurance policies or contracts provide coverage for childhood immunizations. P.L. 1995, c. 316, §§ 1 through 6 (as codified, N.J.S.A. 17:48E-34.1, 17:27-46, 26:2J-4.10, 17B:27A-7,

and 17B:27A-19, respectively) require that all health insurance contracts delivered, issued, or renewed in New Jersey provide coverage for childhood immunizations. In accordance with the statutes, insurers, health service corporations, hospital service corporations and HMOs (collectively, "carriers") are required to cover all immunizations recommended by the Advisory Committee on Immunization Practices (ACIP) of the United States Public Health Services and, in certain instances, the Department.

The Department promulgated N.J.A.C. 8:57-8 pursuant to the authority of P.L. 1995 c. 316, §7 (as codified, N.J.S.A. 26:2-137.1) in order to set forth standards for the provision of immunization benefits or services applicable to carriers offering and renewing group policies or contracts that are not otherwise regulated by the Small Employer Health Benefits Program Board of Directors. (The Department notes that individual policies or contracts are subject to regulation by the Individual Health Service Program Board of Directors with respect to the provision of childhood immunizations.) The Department intends N.J.A.C. 8:57-8 to effectuate the Department's authority with respect to childhood immunizations and health policies and contracts offered and renewed in the "large" employer group market.

N.J.A.C. 8:57-8 sets forth and would continue to set forth the purpose and scope of the subchapter and definitions of words and terms used throughout the subchapter. N.J.A.C. 8:57-8 requires and would continue to require carriers to provide services or benefits for immunizations recommended by the ACIP, and

immunizations recommended in other circumstances as well. Specifically, the rules at N.J.A.C. 8:57-8 require and would continue to require carriers to provide coverage for immunizations recommended outside of the ACIP schedule as necessary to avoid or mitigate declared outbreaks of a communicable disease; when more commonly administered vaccines are contraindicated; or when otherwise medically appropriate to assure that children at higher risk for certain communicable diseases that are vaccine-preventable are adequately immunized. N.J.A.C. 8:57-8 continues to require carriers to cover immunizations rendered outside of the ACIP age recommendations but which nevertheless complete the ACIP recommended schedules, and vaccine doses that repeat doses administered at an earlier time which have since become invalid for the population as a whole, or for the specific child.

N.J.A.C. 8:57-8 would continue to set forth that, while a carrier cannot require satisfaction of any deductible prior to benefits being provided for immunizations, a carrier may still require that a co-payment be satisfied. However, the co-payment must be consistent with the co-payment that would apply for a routine office visit, except that a co-payment cannot be charged to children in Medicaid and enrolled in New Jersey FamilyCare Plans A, B, C, and D.

The Department proposes a new rule at N.J.A.C. 8:57-8.2 to set forth the documents that the Department is incorporating in this subchapter. The Department proposes to incorporate by reference the 2007 Advisory Committee

on Immunization Practices (ACIP), Recommended Childhood and Adolescent Immunization Schedule, as amended and supplemented and the applicable ACIP Recommendations pertaining to each recommended licensed vaccine and its utilization to prevent certain vaccine preventable diseases.

The Department proposes to recodify existing N.J.A.C. 8:57-8.2 as N.J.A.C. 8:57-8.3. The department proposes amendments at recodified N.J.A.C. 8:57-8.3 to add the following new definitions, "Hepatitis A," "NJ Family Care," and "Tdap." The Department proposes amendments at recodified N.J.A.C 8:57-8.3 to supplement or clarify the following existing definitions: "DTap" and "Pneumococcal vaccine." The Department proposes an amendment at recodified N.J.A.C 8:57-8.3 to remove the definition of "Commissioner" since that word is defined under recodified N.J.A.C. 8:57-1.3, which the Department proposes to be applicable to the entire chapter.

The Department proposes to recodify N.J.A.C. 8:57-8.3 as N.J.A.C. 8:57-8.4. The Department proposes to amend recodified N.J.A.C. 8:57-8.4(b)1 and 2, and (d) to replace the formerly titled " Recommended Childhood Immunization Schedule," as published by the U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, with the now incorporated by reference, as amended and supplemented, 2007 Recommended Childhood and Adolescent Immunization Schedule and add the ACIP Recommendations as set forth at new N.J.A.C. 8:57-8.2. The Department also proposes to amend recodified N.J.A.C. 8:57-8.4(c)1 to establish that the program formally known as

New Jersey KidCare is now named "NJ FamilyCare" in order to state the current name of the program. The Department proposes to recodify existing N.J.A.C. 8:57-8.4 as N.J.A.C. 8:57-8.5 without making any changes.

N.J.A.C. 8:58: Reportable Occupational and Environmental Diseases, Injuries, and Poisonings.

The Department proposes to readopt and recodify existing N.J.A.C. 8:57-3 as N.J.A.C. 8:58. The Department proposes grammatical and technical amendments to update the chapter title and clarify the reporting process. The Department proposes a new rule at N.J.A.C. 8:58-1.1, which would establish the purpose and scope of the chapter. The purpose of the chapter is to provide a framework for hospital and health care provider reporting of occupational and environmental diseases, injuries, and poisonings to the Department in order to monitor and prevent these conditions.

The Department proposes a new rule at N.J.A.C. 8:58-1.2, which would set forth documents that the Department incorporates by reference in the chapter. The Department incorporates by reference the Occupational and Environmental Disease, Injury, or Poisoning Report by Health Care Provider (OCC-31) (Appendix), which is the form required of a health care provider in order to report an occupational or environmental disease, injury, or poisoning to the Department.

The Department proposes a new rule at N.J.A.C. 8:58-1.3 which would set forth definitions of the following words and terms used throughout the chapter: "administrator," "Commissioner," "confirmed work-related asthma,"

"Department," "discharge summary," "health care provider," "hospital," "hospital discharge data," "possible work-related asthma," and "probable work-related asthma." The proposed new definition of health care provider includes physicians, physician assistants, nurse practitioners, and clinical nurse specialists. Physician assistants would now be required to report occupational and environmental diseases, injuries, and poisonings to the Department under N.J.A.C. 8:58.

Existing N.J.A.C. 8:57-3.1 proposed for recodification as N.J.A.C. 8:58-1.4 sets forth, and would continue to set forth the requirements for hospital reporting of occupational and environmental diseases, injuries, and poisonings. The Department requires, and would continue to require, reporting of the following occupational and environmental diseases: carpal tunnel syndrome, coal workers pneumoconiosis, asbestosis, silicosis, extrinsic allergic alveolites, and other specified occupational lung diseases and poisonings from various heavy metals and chemicals. The Department proposes grammatical and technical amendments clarify the reporting process, including the method and format of reporting.

Existing N.J.A.C. 8:57-3.2 proposed for recodification as N.J.A.C. 8:58-1.5 sets forth, and would continue to set forth, the requirements for health care provider reporting of occupational and environmental diseases, injuries, and poisonings. The Department requires and would continue to require reporting of the following occupational and environmental diseases, injuries, and poisonings:

asbestosis; silicosis; pneumoconiosis, other and unspecified; work-related asthma (possible, probable, and confirmed); extrinsic allergic alveolitis; work-related carpal tunnel syndrome; adult lead, arsenic, mercury, or cadmium toxicity, work-related fatal injury, poisoning caused by known or suspected occupational exposure; work-related injury in children (under age 18); pesticide toxicity; occupational dermatitis; and other occupational diseases. In the existing rule, the Department requires reporting by physicians and advanced practice nurses. In this rulemaking, the Department's proposed definition of health care provider includes physicians, physician assistants, nurse practitioners, and clinical nurse specialists. The Department proposes amendments at recodified N.J.A.C. 8:58-1.5(b)4, 14, and 16 to specify that healthcare providers should report possible, probable, and confirmed cases of work-related asthma instead of occupational asthma, cases of work-related carpal tunnel syndrome instead of carpal tunnel syndrome, and cases of other occupational diseases. At recodified N.J.A.C. 8:58-1.5(c), the Department proposes an amendment to require reporting using the Report of Occupational and Environmental Disease, Injury, or Poisoning by Health Care Provider (OCC-31) form, available in the proposed chapter Appendix.

Existing N.J.A.C. 8:57-3.3 proposed for recodification as N.J.A.C. 8:58-1.6 establishes, and would continue to establish, confidentiality provisions with regard to the patient information collected by hospitals and health care providers in connection with the Department's required reporting of occupational and

environmental diseases, injuries, and poisonings. The Department proposes an amendment at N.J.A.C. 8:58-1.6(a) to establish that the medical and demographic information reported by hospitals and health care providers are not government records within the meaning of N.J.S.A. 47:1A-1 et seq. The Department also proposes grammatical amendments to clarify the existing confidentiality provisions.

The Department proposes a new rule at N.J.A.C. 8:58-1.7, which would establish that there is a penalty for hospital administrators and health care providers for non-compliance with any provision of recodified N.J.A.C. 8:58 pursuant to N.J.S.A. 26:1A-10.

Proposed Amendments to Other Rules

As previously mentioned, the Department proposes amendments to several other rules under N.J.A.C. 8 to correct their existing citations to sections under N.J.A.C. 8:57-1 and 2, which the Department has proposed for readoption with amendments and recodification in this rulemaking. The Department proposes an amendment at N.J.A.C. 8:36-18.4(a)1 to change the existing citation from N.J.A.C. 8:57-1.3(a) and (b) to N.J.A.C. 8:57-1.5. The Department proposes an amendment at N.J.A.C. 8:39-27.4(e) to change the existing citation from N.J.A.C. 8:57-1.2 to N.J.A.C. 8:57-1.3. The Department proposes an amendment at N.J.A.C. 8:43D-15.4(m) to change the existing citation from N.J.A.C. 8:57-1.3(a) and (b) to N.J.A.C. 8:57-1.5. The Department proposes an amendment at N.J.A.C. 8:43H-20.2(b)7 to change the existing citation from N.J.A.C. 8:57-2.7 to

N.J.A.C. 8:57-2.11. The Department proposes an amendment at N.J.A.C. 8:52-12.3(d) to change the existing citation from N.J.A.C. 8:57-1.3 to N.J.A.C. 8:57-1.5.

Social Impact

N.J.A.C. 8:57-1: The readoption of this subchapter and the implementation of the proposed amended reporting requirements will have a beneficial social impact. Communicable diseases continue to be a leading cause of preventable morbidity and mortality. Reporting of individual cases of communicable diseases by physicians, advanced practice nurses, hospitals, other health care institutions, and laboratories alerts public health officials to potential communicable disease problems and/or outbreaks and makes early intervention possible. The prevention and/or limitation of the spread of outbreaks of these illnesses continue to be among the most cost-efficient methods of spending limited public health dollars. Prevention of these illnesses improves the general well being of the public, limits time lost from work due to illness, and limits costs of treatment for these illnesses. Without these rules proposed for readoption with amendments, identification of outbreaks and other communicable disease problems would be delayed, leading to a delay in the implementation of control measures and thus allowing more individuals to become ill. These proposed amendments simplify and clarify reporting requirements and add provisions for confidentiality of reported information, ensuring a more complete and confidential communicable disease control system. The proposed new rule

requiring reporting of zoonotic diseases in domestic companion animals would have a beneficial social impact by alerting public health officials of potential communicable diseases transmissible to humans from domestic companion animals. The proposed new rules regarding zoonotic diseases would make early intervention possible, thereby reducing transmission of zoonotic diseases to people.

N.J.A.C. 8:57-2: Since June 1981, 68,207 cumulative HIV and AIDS cases in New Jersey have been reported in a manner consistent with the national surveillance reporting system for HIV and AIDS by the Center for Disease Control and Prevention (CDC) of the United States Public Health Services. Additionally, New Jersey ranks fifth in cumulative AIDS cases, third in cumulative pediatric cases and has the highest proportion of women living with AIDS. Estimates suggest that 45,000 New Jersey residents are thought to be infected with HIV and one-third remain unaware of their status. The information collected using the existing surveillance and Counseling and Testing (CAREware) reporting system for HIV will allow the Department to continue with the monitoring, collection and reporting on the impact of HIV in New Jersey.

The proposed readoption with amendments and new rules of N.J.A.C. 8:57-2, Reporting of Acquired Immunodeficiency Syndrome (AIDS) and Infection with Human Immunodeficiency Virus (HIV) would establish a framework for reporting HIV cases, thus allowing the Department to evaluate and improve service delivery for individuals affected and living with HIV. The

proposed new rules at N.J.A.C.8:57-2.2 would provide the methods, forms and instructions for medical practitioners, clinical laboratory directors, responsible parties to report HIV and AIDS cases. The required reporting of children perinatally exposed to HIV infection to the Department in subchapter 2, has resulted in reducing the mother-to-child HIV transmission by promoting early diagnosis and HIV rapid testing. Mother-to-child HIV transmission in New Jersey has decreased from 88 infected children (24 percent of exposed children) in 1993 to 3.7 percent in 2005 (seven of the 189 exposed children). The proposed readoption with amendments of this requirement would have a beneficial social impact by continuing to reduce mother-to-child HIV transmission and promoting early diagnosis. Finally, the proposed readoption with amendments and new rules is expected to have a favorable social impact on all patients by requiring clinical laboratories to submit remnant blood specimens to the PHEL for identification of early HIV infections, thereby allowing for earlier diagnosis and treatment.

N.J.A.C. 8:57-3: N.J.A.C. 8:57-3 would be reserved for future use. The Department will discuss recodified N.J.A.C. 8:58 below.

N.J.A.C. 8:57-4: The rules proposed for readoption will have a positive social impact by permitting appropriately licensed health care providers to provide mandated vaccine-related services, and by keeping the rules consistent with accepted medical practice. Vaccine-preventable diseases remain a threat to school-aged and preschool-aged children. Prevention of such disease cases and outbreaks requires high immunization levels among school-aged and preschool-

aged children. A continued high level of protection will prevent these disease cases and outbreaks and their after-effects by curtailing the associated high social costs that affect the individual, the family, and the community.

The proposed amendment at N.J.A.C. 8:57-4.6(c) would have a beneficial social impact by articulating that the submission of laboratory evidence of protective immunity is another method by which a parent or guardian may prove a child's immunization, thereby preventing that child from having to obtain duplicative immunizations. The proposed amendments at N.J.A.C. 8:57-4.18(a) and (b) would include the children that attend preschool facilities in the PCV requirements and would have a positive social impact by protecting preschoolers and those that come in contact with them from this disease. Such inclusion is important because this bacterium is the leading cause of bacterial meningitis in the United States and up to 60 percent of children are carriers of this bacterium but do not exhibit any symptoms or develop the disease. In recent years, this bacterium has become more resistant to antibiotics thereby making it more difficult to find life-saving therapies. The demand for, and acceptance of, this vaccine by medical practitioners and parents has already had a significant impact on reducing the incidence of disease among preschool-aged children and has had a secondary positive effect of also reducing disease among older children and adults.

N.J.A.C. 8:57-5: The readoption of this subchapter and the implementation of the proposed amended and new reporting and management

requirements will have a beneficial social impact on all persons in this State with tuberculosis (TB) disease; their contacts; other persons with latent TB infection; and recent immigrants or refugees with a B1 or B2 classification. Although the TB rate continues to decline in the United States, the rate of decline has slowed since 2000. The TB rate among foreign-born persons in the United States, although declining, remains 9.5 times that of U.S.-born persons. Reporting and appropriate management of individual cases of tuberculosis by physicians, advanced practice nurses, health officers, hospitals, other health care providers, and laboratories is a proven methodology, which maximizes the control of this deadly disease in a cost effective manner, and prevents spread of tuberculosis to other individuals. These proposed amendments and new rules clarify reporting and management requirements, clarify penalties for failure to comply, and add provisions for confidentiality of reported information. Those provisions will have a positive social impact on the required reporters listed above by detailing necessary actions to comply with the rules, thereby assuring appropriate management of TB patients and a lower spread of disease; informing them of potential consequences of noncompliance in advance; and alerting them of the circumstances under which submitted information is confidential, which may make compliance with the rules easier.

N.J.A.C. 8:57-6: National and state morbidity data reveal that the majority of hepatitis B cases occur among older adolescents and young adults. Hepatitis B remains a serious and insidious disease where approximately 50

percent of infected persons show no early signs or symptoms of disease and can unknowingly pass the virus on to others through exposure to the blood or other bodily fluids of infected persons. Persons who become chronically infected can die from liver disease. There is no generally available and efficacious drug or therapy to fight this virus. The only medically available intervention to protect individuals is to administer hepatitis B vaccine before exposure to prevent this serious and potentially life threatening virus. In November 1996, the national Advisory Committee on Immunization Practices (ACIP) recommended that all states implement school vaccination requirements for all adolescents, to include hepatitis B vaccine. On December 23, 2005, the ACIP recommended that all students entering college receive the hepatitis B vaccine, when feasible and the recommendation is accessible at www.cdc.gov/mmwr/PDF/rr5416.pdf. The proposed amendments at N.J.A.C. 8:57- 6.16(a) and (b) would permit the wider use of electronic means related to the dissemination of, and the submission of, completed Annual College Immunization Status Reports from institutions. This proposed amendment recognizes the increased computerization in society and would also improve operating efficiencies related to the data collection, compilation, monitoring, and analysis of vaccine coverage data and the assessment of higher education institution compliance with the requirements of this subsection. The proposed readoption of this subchapter with amendments and new rules will help ensure a continued high level of protection against the occurrence of individual cases and prevent outbreaks of the five diseases the

vaccines protect against. The prevention of these diseases has a positive social benefit affecting the individual, the family, the college community, and the wider community.

N.J.A.C. 8:57-7: Education beyond the high school level is voluntary. Hence, these rules proposed for readoption will impact only those who choose to attend New Jersey's public and private colleges and universities as full-time students. In 2006, approximately 349, 248 students were enrolled in New Jersey institutions of higher education. Of these, approximately 50 percent were full-time students who would be required to maintain health insurance coverage. Colleges and universities have been mandated to ensure health insurance coverage for all full-time students since 1991. The provisions of N.J.S.A. 18A:62-15 and the rules at N.J.A.C. 8:57-7 afford protection to these students from the insurmountable costs of catastrophic illnesses or injuries requiring hospitalization. Also, the fragility of funding for charity care provided by New Jersey hospitals underscores the importance of keeping this population in a payer status. Group rates and the actuarial record of young adults make coverage affordable to most students who are not already covered under their parent's family coverage health insurance plans. Affordable rates and government subsidized health insurance for the poor make coverage attainable for each student.

N.J.A.C. 8:57-8: Vaccine-preventable diseases can produce catastrophic effects, especially in young children. During outbreaks, which have occurred over the past 20 years in New Jersey, thousands of people suffered the effects of

vaccine preventable diseases, which include complications, hospitalizations, and some deaths. In measles outbreaks, children accounted for most cases and approximately 25 percent of the hospitalizations and four of the seven deaths. For adults affected, the loss of time from work was substantial.

Since 2000, there have been seven vaccines that have been either added to the routine immunization schedule as a newly licensed vaccine, or as an existing licensed vaccine recently recommended for administration to all children and adolescents. These new ACIP recommended vaccines include the following: pneumococcal conjugate vaccine, meningococcal conjugate vaccine, rotavirus vaccine, hepatitis A vaccine, influenza vaccine, human papilloma virus vaccine, and tetanus and reduced diphtheria and acellular pertussis (Tdap) vaccine. The continued implementation and widespread use of these vaccines will help prevent future morbidity, complications, hospitalizations, and deaths from the diseases the vaccines protect against.

The Department is proposing the readoption with amendments of these rules so that those children and families covered by health insurance policies issued to groups with greater than 50 people will be given the broadest access to immunizations as is permissible under the law and to support the pediatric medical home for each child. The readoption of these proposed rules would continue to provide open access to immunizations for a large proportion of New Jersey preschool and school-age children. The continued access to immunizations is expected to promote the improvement of immunization rates within New

Jersey, thereby increasing the protection of the entire State's population against widespread outbreaks of vaccine-preventable diseases. The readoption of these rules is necessary to sustain the recent improvements related to providing access to comprehensive and quality medical care, rising immunization coverage rates, and decreasing the number of cases of vaccine-preventable disease cases, especially pertussis cases among adolescents, which are now being reported in New Jersey.

N.J.A.C. 8:58: Persons exposed to hazardous substances in the workplace and the environment are continually at risk for occupational and environmental disease, injury, and poisoning. Persons injured on the job endure pain and suffering and incur medical costs. The rules proposed for readoption have established a framework that requires reporting of individuals diagnosed with illnesses associated with these exposures. The reporting of these diagnoses provides the Department with information that identifies sources of exposure and thus initiates appropriate preventive public health actions. The rules proposed for readoption have allowed, and would continue to allow, the Department to collect information to initiate (1) industrial hygiene investigations to evaluate existing exposure controls and to provide recommendations for improving controls; (2) referrals to other governmental agencies such as local health departments, the Occupational Safety and Health Administration (OSHA), the Public Employees Occupational Safety and Health Programs in the Departments of Health and Senior Services and Labor and Workforce Development, and the New Jersey

Department of Environmental Protection.; (3) epidemiologic investigations of populations of workers exposed to toxic substances; and (4) education and outreach programs targeted at the worker, employer, and the health care provider. Since the promulgation of the occupational and environmental disease, injury, and poisoning reporting rules, the Department has received numerous disease reports from hospitals and physicians that have led to the implementation of preventive measures. These rules proposed for readoption have helped to safeguard, and will continue to help safeguard, the health of workers and residents of New Jersey. The Department proposes grammatical and technical amendments throughout proposed N.J.A.C. 8:58 in order to clarify existing sections. Those proposed amendments would have no social impact. The Department's proposed amendment to add N.J.A.C. 8:58-1.3 would establish the definitions of words and terms used throughout the chapter, which would clarify the reporting process and allow hospitals and health care providers to comply with the requirements. The Department's proposed amendment at N.J.A.C. 8:58-1.5(b)4, 14, and 16 would allow the Department to capture more useful information about work-related asthma, work-related carpal tunnel syndrome, and other types of work-related diseases, injuries, or poisonings, which would allow for more efficient follow-up of these cases. The Department's proposed amendment at N.J.A.C. 8:58-1.6(a) would establish that the medical and demographic information reported to the Department is not considered government records and therefore not subject to public access. The proposed amendment at N.J.A.C. 8:58-1.6(a) would safeguard

the medical information of persons suffering from occupational and environmental illness, injury, and poisoning while allowing the Department to carry out its public health mandate.

Proposed Amendments to Other Rules: The Department's proposed amendments to N.J.A.C. 8:36-18.4, 8:39-27.4, 8:43D-15.4, 8:43H-20.2, and 8:52-12.3 are technical to correct citations, which would be recodified as a result of this rulemaking. The proposed amendments would allow the regulated entities applicable to the sections proposed for amendment above to proceed with the correct information, thereby fulfilling the mandates of those rules and ensuring the protection of public health.

Economic Impact

N.J.A.C. 8:57-1: There are some costs associated with the rules proposed for readoption with amendments and proposed new rules. These include costs in staff time to complete reports on paper, costs of postage and/or telephone costs. Health care providers and institutions would be required to report up to 50 additional communicable diseases with these amendments. Almost all of these additional diseases, with the exception of Salmonellosis and Shigellosis, are very rare occurrences, although when they occur, they are of major public health significance. The importance of prompt notification followed by actions to reduce or prevent the spread of disease outweighs the costs to any given physician's office or other impacted health care setting. The Department

proposes to require electronic laboratory reporting effective as of September 1, 2010. The Department anticipates that for larger laboratories, the additional costs in software to enable electronic laboratory reporting would be offset in part by the cost savings in staff time and postage to produce and mail paper reports. Smaller laboratories with lower volume may choose to do electronic reporting if electronic laboratory reporting is not available because of high costs. Any additional cost to laboratories for electronic laboratory reporting is dependent on their existing software and hardware.

N.J.A.C. 8:57-2: The proposed readoption with amendments and proposed new rules would require clinical laboratories to send residual specimens to the State laboratory for further HIV analysis and testing. This would allow the Department to identify the number of new HIV infections. As a result, this would enhance the Department's ability to monitor and evaluate the impact of the epidemic. Studies have shown that early diagnosis allows individuals to receive early treatment and care resulting in improved health and extended life. In many cases, early diagnosis of HIV can often slow the progression of disease thereby avoiding hospitalization and long-term care. The beneficial economic impact of this is that individuals can continue to work and be productive. Currently many people learn of their HIV infection only after they have developed symptoms. The economic benefit of detecting HIV infections early is in the best interest of consumers. Since most laboratories in New Jersey are currently sending their specimens to the State laboratory, it is anticipated that the additional costs of

sending residual blood will be minimal. In addition, because clinical laboratories routinely utilize courier services for transporting all types of specimens to the State laboratory the costs should be minimal. These costs will vary depending on the number of specimens sent by clinical laboratories to the PHEL. Because of these variables, it is not practical to estimate the costs to the laboratories. However, the Department will supply the labels and containers to help defer some of the costs to the laboratories.

N.J.A.C. 8:57-3: N.J.A.C. 8:57-3 would be reserved for future use. The Department will discuss recodified N.J.A.C. 8:58 below.

N.J.A.C. 8:57-4: The readoption of N.J.A.C. 8:57-4 would not increase the economic cost to the parents or guardians of pupils entering school or preschool settings, or to health care providers. Despite increasing vaccine costs for disease prevention, which are borne by the family, insurers, and public and private health providers alike, the economic costs associated with outbreaks of vaccine-preventable diseases are at least 10 times greater. These costs may include hospitalization, lost class time for ill pupils, parental loss of work time, chronic illness, premature death, and disruption of routine school and health delivery activities.

The proposed amendment at N.J.A.C. 8:57-4.6(c) may decrease economic costs to parents or guardians by allowing another means to prove immunity which would prevent those children with laboratory evidence of protective immunity from having to obtain additional doses of vaccine. The proposed amendments at

N.J.A.C. 8:57-4.18(a) and (b), correcting the age bracket of children required to have the PCV in order to enroll in or attend preschools, would have little or no effect on costs to the existing medical system. Since 1999, PCV has been a routine vaccination for all children during infancy as a standard medical practice and is given at the same pediatric office visit as the other pediatric vaccines medically recommended or specifically mandated by this subchapter. National vaccine coverage surveys conducted by the CDC for 2004 indicated that 78.9 percent of New Jersey's children 19 through 35 months of age had received the PCV vaccine.

N.J.A.C. 8:57-5: The proposed readoption with amendments and proposed new rules at N.J.A.C. 8:57-5 may have an adverse economic impact on hospitals. N.J.A.C. 8:57-5.5 as proposed would require that specific criteria be met prior to hospital discharge. N.J.A.C. 8:57-5.5 would require that living situations be verified as accurate and stable and vulnerable populations residing in the household be tested for LTBI prior to hospital discharge. The magnitude of this adverse economic impact may be reduced by notifying the Department's TB Program or local designee as soon as a smear positive for AFB is reported for a hospital inpatient. Public health will verify the address as to validity and stability and complete tuberculin skin testing of co-residents to minimize or prevent delays in discharge. The proposed requirement to delay hospital discharge for an inpatient with an initial smear positive for AFB without a stable address or residing in a congregate setting until three smears, collected at least eight hours

apart, are reported negative for AFB or one culture is reported negative for *M.tuberculosis,* may also have an adverse economic impact on hospitals. For hospitals with a historically high percentage of inpatients with initial smears positive for AFB and cultures that are non-tuberculous mycobacteria, the routine ordering of nucleic acid amplification testing for AFB smear positive inpatients would reduce costs associated with this proposed requirement. A nucleic acid amplification test negative for *M.tuberculosis* would immediately relieve the hospital from any proposed discharge requirement under this subchapter. The cost of this laboratory testing is low compared to the cost of continued hospitalization in an airborne infection isolation room. Although resulting in an adverse economic impact for the hospital, this requirement is essential to prevent avoidable transmission of TB in the community.

The Commissioner's designation of a hospital as the location of service for a health officer order for temporary commitment or court commitment for a person with suspected or confirmed infectious or potentially infectious TB disease posing an imminent risk to the public health may also have an adverse economic impact on hospitals. This impact is not predicted to be significant, because the use of commitment to manage non-adherent TB patients is a relatively rare occurrence in New Jersey. Third party payers, including charity care, may reduce this economic impact. The proposed contingency to specify a private residence as a site of commitment should further decrease the negative economic impact on

hospitals. In the past, hospitals were the only settings where commitment could be served.

The implementation of N.J.A.C. 8:57-5.6 as proposed would have no adverse economic impact on most counties or local health jurisdictions in New Jersey. In fact, agreements made under this rule with existing regional TB specialty clinics funded in part by the Department may actually reduce the current cost for the provision of these essential services. Only in a small number of counties in New Jersey where these essential services have not been available or have been entirely dependent upon Departmental funding, would this rule have an adverse economic impact on the county or local health jurisdictions, but even in these locations, the costs associated with agreements with existing regional TB specialty clinics would be substantially lower than the costs of providing these services independently. The Department does not anticipate any additional economic costs to health care providers or specialty clinics because of the proposed readoption with amendments or proposed new rules.

N.J.A.C. 8:57-6: These rules proposed for readoption with amendments and proposed new rules would have a minimum economic impact on New Jersey institutions of higher education and on the students. With the implementation of the proposed amendment at recodified N.J.A.C. 8:57-6.17(a)1 there may be a cost savings, which would accrue to those institutions using the electronic reporting format for submission of the Annual College Immunization Status Report to the Department. The economic impact on the institutions would be those incremental

costs related to providing information about the proposed new hepatitis B vaccination requirement at N.J.A.C. 8:57-6.9 included in their admission packets, which are routinely sent to all new matriculating students. Other incremental costs that would be incurred by institutions due to the addition of hepatitis B vaccine to the list of required vaccines relate to the closer review of student immunization records and the assessment of student compliance with the proposed new rule necessary for the submission of the Annual College Immunization Status Report to the Department. Two and four year institutions affected by the hepatitis B vaccine law would be required to offer hepatitis B vaccine through their institution's student health services program or through a contractual agreement with a community health care provider, as directed by N.J.S.A. 18A:61D-9c. Little additional labor costs would be incurred by the institution's health center, since this vaccine would be added to those already being administered by the institution or where past vaccinations documentation are already being requested of the new student. These institutions are exposed to minimal economic risk regarding the purchase vaccine since each student is routinely charged for any institution vaccination service.

Over time the proposed amendment at recodified N.J A.C. 8:57-6.13(a)4 would save time and costs for institutions, physicians, and students, as they would find it easier to provide documentation of those vaccines previously administered and required in this subchapter. The proposed amendments at N.J.A.C. 8:57-4.5, 4.6, and 4.7 would provide a four day grace period for some students who

received a vaccine too early that will no longer have to be revaccinated, thereby saving additional health costs to the physician community and the student. Generally, the proposed new hepatitis B rule at N.J.A.C. 8:57-6.9 would have no economic impact on most students entering an institution from a New Jersey high school. By September 2008, all New Jersey pupils in grades K-12 must have been previously compliant with the equivalent hepatitis B requirement for pupils in public and non-public schools. These rules would also have a minimal impact upon the student who chooses to seek a hepatitis B vaccination or who previously was not required to receive one while attending a secondary school or another college in another state or another country. Generally, most institutions directly charge the student approximately $60 to $165 to help defray the institutions' cost of purchasing the hepatitis B vaccine doses from a pharmaceutical company or wholesaler. Some institutions also add a minimal administration fee of approximately $10 for administering and documenting the dose. These costs for services at a student health service are often less than costs incurred if vaccination services are provided at the student's private physician, who may also charge an office visit fee. A student may file a claim with his or her insurance company to receive reimbursement; however, this reimbursement is dependent upon the provisions contained within the student's or parent's individual health plan or health indemnity policy in force. Many health maintenance organizations, and some indemnity health plans, may cover this cost, but these private health insurance matters are the sole responsibility of the patient. All full-time students

at institutions of higher education are required to have health insurance (N.J.A.C. 8:57-7.4(b)). The cost of the hepatitis B vaccination is reasonable when compared to the costs associated with medical complications and sequelae such as lifelong chronic infection and cirrhosis of the liver, hospitalization, and possible death due to infection.

N.J.A.C. 8:57-7: The rules proposed for readoption without amendments would have little or no cost upon the regulated community. The statute requiring health insurance for all full-time students enrolled in private or public colleges and universities has been in effect for more than 15 years, and all institutions should have already been in compliance with the statute by providing students with access to health insurance coverage. There may be an administrative cost for those institutions, which have not been keeping records for evidence of compliance. These costs should be minimal, however, and are unavoidable if the Department is to be responsible for oversight and compliance with this law. Keeping the higher education full-time student population insured for basic hospitalization also benefits New Jersey's hospitals, which would otherwise be faced with a proportion of this population becoming charity care patients.

N.J.A.C. 8:57-8: These rules proposed for readoption with amendments and a new rule would have a modest economic impact on insurance carriers and it is likely that these costs would be passed on to employers and individuals in the form of increased insurance premiums. Since 2000, there have been seven new vaccines licensed and/or universally recommended for universal administration to

all children and adolescents. These new vaccines are more costly than other vaccines licensed decades ago. Private physicians and public clinics have to expend more funds to procure these newer vaccines, and carriers will have to cover these vaccines for their policyholders, which have become the standard of medical care. In 1995, the federal contract vaccine price for the 10 vaccines routinely recommended for children and adolescents to attain complete immunization in a child was $155. By 2007, the federal contract vaccine price for the 16 vaccines now routinely recommended for children and adolescents to attain complete immunization is about $900 to $1200. The private sector vaccine costs are generally greater than the federal contract vaccine prices. These costs are counterbalanced by the costs to society if diseases are not prevented through vaccination. The investment in immunizations by the government, employers, insurance companies, and individuals will help to decrease long-term costs associated with vaccine-preventable diseases. Past estimates have stated that $10 in future health care costs are averted for each one dollar that is spent to provide appropriate immunizations to children.

It is probable that these rules will have an adverse economic impact on carriers, though the degree of the impact will vary from one carrier to another. Carriers offering managed care products likely will incur only modest increases, if any at all, because managed care products have traditionally covered well-baby and well-child services, including immunizations. Traditional indemnity products have only recently begun providing benefits for such services and the carriers

offering these products may interpret the instances in which immunizations must be covered more narrowly than as set forth in these rules. Thus, the economic impact on traditional indemnity carriers, or carriers with portfolios of products emphasizing traditional indemnity may experience greater cost increases than carriers with managed care products predominant in their market strategies.

The economic impact upon carriers is likely to be passed on, in whole or part, to employers in the form of increased premiums and subsequently to individuals who may be asked by their employers to contribute to any increase in health insurance premiums. These increased costs, however, are necessary to comply with the provisions of P.L. 1995, c.316.

N.J.A.C. 8:58: The rules proposed for readoption with amendments impose costs on hospitals and health care providers that are associated with the reporting of occupational and environmental diseases, injuries, and poisonings to the Department. The reporting of diagnoses by hospitals under N.J.A.C. 8:57-3.1 proposed for recodification as N.J.A.C. 8:58-1.4 constitutes negligible economic impact to these institutions because occupational and environmental diseases, injuries, and poisonings are identified from electronic hospital discharge data that is already reported to the Department under N.J.S.A. 26:2H-1 et seq. and N.J.A.C. 8:31B-2. The major cost to the 81 hospitals that provide acute care will be administrative costs associated with providing additional information that may be required by the Department. The reporting of occupational and environmental diseases, injuries, and poisonings by health care providers under N.J.A.C. 8:57-

3.2 proposed for recodification as N.J.A.C. 8:58-1.5 constitutes a marginally significant economic impact to this group, primarily associated with the administrative costs of reporting and providing additional information to the Department.

Economic costs to hospitals and health care providers can be viewed against the economic benefits derived from reducing occupational and environmental illness, injury, and poisoning among workers and the public. Such benefits are significant not only for workers at risk for developing occupational and environmental diseases, injuries, and poisonings but also to employers who must compensate affected workers for their health care costs. Costs from lost wages, workers' compensation, and medical expenses will be reduced by a decrease in the incidence of occupational and environmental illness, injury, and poisoning.

Cases of occupational and environmental illness, injury, and poisoning comprise only a small percentage of physician caseload. Thus, the Department believes the economic impact of the rules proposed for readoption on health care providers is minimal. As with hospital reporting, the minimal costs to physicians can be viewed against the economic benefits from reducing occupational and environmental illness and injury in the State.

The Department's proposed amendment of N.J.A.C. 8:58-1.5(b)4 and 16 may result in an increase of reporting costs for health care providers because the requirement now includes suspected cases of work-related asthma in addition to

confirmed cases, as well as a requirement to report other occupational diseases. Conversely, the Department's proposed amendment of N.J.A.C. 8:58-1.5(b)14 may result in a decrease of reporting costs for health care providers because the requirement applies to only work-related cases of carpal tunnel syndrome.

Proposed Amendments to Other Rules: The Department's proposed amendments to N.J.A.C. 8:36-18.4, 8:39-27.4, 8:43D-15.4, 8:43H-20.2, and 8:52-12.3 are technical to correct citations, which would be recodified as a result of this rulemaking. These proposed amendments would have no economic impact.

Federal Standards Statement

N.J.A.C. 8:57-1: The readoption of N.J.A.C. 8:57-1 with amendments and new rules is not proposed under the authority of, or in order to implement, comply with, or participate in, any program established under Federal law or under a State statute that incorporates or refers to Federal law, Federal standards, or Federal requirements. Therefore, a Federal Standards Analysis is not required.

N.J.A.C. 8:57-2: The proposed readoption with amendments, repeals and new rules do not impose requirements on medical practitioners, responsible parties and clinical laboratories that exceed those contained in Federal laws or regulations. Since there is currently no Federal law governing the reporting of HIV/AIDS, as described herein, a Federal Standards Analysis is not applicable to this proposed readoption with amendments, repeals, and new rules.

N.J.A.C. 8:57-3: N.J.A.C. 8:57-3 would be reserved for future use. The Department will discuss recodified N.J.A.C. 8:58 below.

N.J.A.C. 8:57-4: The Department is not proposing the readoption of these rules or the proposed amendments under the authority of, or in order to implement, comply with, or participate in any program established under Federal law, or under a State statute that incorporates or refers to Federal law, standards, or requirements. However, in order to establish one medical standard, the Department has elected to use the recommendations of the Advisory Committee on Immunization Practices (ACIP) rather than the vaccine recommendations of other medical advisory bodies. The rules do not impose requirements, which exceed the recommendations of the ACIP and therefore, a Federal Standards Analysis is not required.

N.J.A.C. 8:57-5: The readoption of this subchapter with amendments and repeals and new rules is not proposed under the authority of, or in order to implement, comply with, or participate in any program established under Federal law or under State statute that incorporates or refers to Federal law, standards, or requirements. Therefore, a Federal Standards Analysis is not required.

N.J.A.C. 8:57-6: The rules proposed for readoption with amendments and new rules are proposed pursuant to State statue. The rules proposed for readoption with amendments and proposed new rules do not impose standards on institutions of higher education or health care providers in New Jersey that exceed those contained in federal guidelines as set forth by the Advisory Committee on Immunization Practices (ACIP), U.S. Public Health Service, U.S. Department of Health and Human Services, as published in the December 23, 2005 issue of

Morbidity and Mortality Weekly Report, Volume 54, No. RR-16 Recommendations and Reports: A Comprehensive Immunization Strategy to Eliminate Transmission of Hepatitis B Virus Infection in the United States. Therefore, a Federal Standards Analysis is not required.

N.J.A.C. 8:57-7: The readoption of these rules is not proposed under the authority of, or in order to implement, comply with, or participate in any program established under Federal law or under a State statute that incorporates or refers to Federal law, standards, or requirements. Therefore, a Federal Standards Analysis is not required.

N.J.A.C. 8:57-8: These rules proposed for readoption with amendments and new rules are not proposed under the authority of, or in order to implement, comply with, or participate in, any program established under Federal law, or under a State statute that incorporates or refers to Federal law, standards, or requirements. However, in order to establish one medical standard, the Department has elected to use the recommendations of the Advisory Committee on Immunization Practices (ACIP) rather than the vaccine recommendations of other medical advisory bodies. The rules do not impose requirements, which exceed the recommendations of the ACIP and therefore, a Federal Standards Analysis is not required.

N.J.A.C. 8:58: The rules proposed for readoption and the proposed amendments and new rules are not proposed under the authority of or in order to implement, comply with, or participate in any program established under Federal

law or under a State statute that incorporates or refers to Federal law, standards, or requirements. Therefore, no Federal Standards Analysis is required.

Proposed Amendments to Other Rules: The Department's proposed amendments to N.J.A.C. 8:36-18.4, 8:39-27.4; 8:43D-15.4, 8:43H-20.2, and 8:52-12.3 are technical to correct citations, and are not made pursuant to the authority of or in order to implement, comply with, or participate in any program established under Federal law or under a State statute that incorporates or refers to Federal law, standards, or requirements. Therefore, no Federal Standards Analysis is required.

Jobs Impact

The Department does not expect that any jobs will either be generated or lost as a consequence of the rules proposed for readoption with amendments, proposed repeals, proposed amendments or proposed new rules.

Agriculture Industry Impact

Proposed new N.J.A.C. 8:57-1.8 would require reporting of specified zoonotic diseases, which are a type of communicable disease transmitted between animals and humans and disease outbreaks in domestic companion animals (DCAs) by veterinarians, certified animal control officers, and animal facility managers. Zoonotic disease reporting to public health officials is necessary to prevent the transmission of disease between animals and people through appropriate public health intervention. The Department created the proposed animal disease reporting rules in consultation with the New Jersey Department of

Agriculture (NJDA). The proposed new rules would apply only to communicable diseases diagnosed in DCAs, which are pets as opposed to livestock and poultry. The Department will conduct training and outreach for veterinarians, local health agencies, and other constituents on the proposed reporting requirements and will emphasize that NJDA shall be immediately notified of reports of disease in livestock or disease in other animals that may affect livestock. The NJDA has authority over livestock and poultry disease surveillance, testing, sampling, detection, and investigation, as set forth in N.J.S.A. 4:5. The NJDA definition of livestock and poultry excludes dogs, cats, pet birds and other domestic companion animals.

The Department has regulatory authority to address zoonotic disease transmission from animals to people, as set forth in N.J.S.A. 26:1A-7 and 26:4-1 and 4-2. The following are existing rules promulgated by the Department addressing zoonotic disease transmission from animals to people: N.J.A.C. 8:23-1.1 through 1.5 requires reporting to local health agencies (LHAs) by veterinarians of cases of rabies in animals and avian chlamydiosis in pet birds, and requires veterinarians to examine and certify all dogs imported into the State as free of communicable disease; and N.J.A.C. 8:23A-1.9 establishes the requirements for a disease control and prevention program to be established and maintained by a veterinarian at animal facilities (for example kennels, pet shops, shelters and pounds). Veterinarians serving in this capacity must report to the

LHA when they diagnose a zoonotic disease and when they are no longer responsible for disease control at the facility.

The Department's existing veterinary animal disease requirements have not negatively impacted NJDA's livestock and poultry disease surveillance activities. Veterinarians who treat only DCAs (for example, small animal veterinarians) are familiar with the role of the Department with regard to zoonotic disease reporting, investigation and control. Therefore, proposed N.J.A.C. 8:57-1.8 would supplement and not negatively impact, NJDA's livestock and poultry disease reporting, surveillance, testing, sampling, detection and investigation programs.

The remaining rules proposed for readoption with amendments and the proposed new rules and amendments would not have an impact on the agriculture industry.

Regulatory Flexibility Analysis

N.J.A.C. 8:57-1: The proposed readoption of this subchapter and the addition of the new reporting requirements through proposed amendments and new rules, would impose some additional reporting, recordkeeping, and compliance requirements on businesses, as described in the Summary above, some of which are small businesses as defined by the Regulatory Flexibility Act, N.J.S.A. 52:14B-16 et seq. Small businesses would include small health care provider practices, some clinical laboratories, some preschools, day care centers, veterinary practices and licensed animal facilities.

The rules proposed for readoption with amendments and proposed new rules would be applicable to all health care providers, clinical laboratories, preschools, schools, day care centers, veterinary practices, licensed animal facilities and other institutions (as specified in the rules) without exception, based on size or any other characteristic. The additional reporting, recordkeeping, and compliance requirements may lead to additional costs as described in the Economic Impact above. The statutory provisions being implemented through N.J.A.C. 8:57-1 require universal reporting and application in the interest of preventing the spread of diseases and safeguarding the public health.

N.J.A.C. 8:57-2: The proposed readoption with amendments and new rules would affect clinical laboratories and institutions, which include but are not limited to counseling and testing sites, health care providers, and clinics. While clinical laboratories and some institutions employ over 100 full-time employees, counseling and testing sites, health care providers and clinics may be defined as small businesses, as set forth in N.J.S.A. 52:14B-16 et seq., since they may employ less than 100 full-time staff. These rules would require personnel to perform multiple reporting activities as described in the Summary above with the attendant costs described in the Economic Impact above. The Department believes the reporting and compliance requirements are necessary in order to enhance the efforts taking place to halt the further spread of the epidemic. Because reporting must be complete to be useful in the provision of services or

for statistical data, no exemption or lesser requirements can be provided for small businesses.

N.J.A.C. 8:57-3: N.J.A.C. 8:57-3 would be reserved for future use. The Department will discuss recodified N.J.A.C. 8:58 below.

N.J.A.C. 8:57-4: The rules proposed for readoption and the proposed amendments would continue to have an impact on some small businesses as defined in N.J.S.A. 52:14B-16 et seq., such as physicians' offices, child care centers, preschools, and schools that employ less than 100 full time persons. The rules proposed for readoption would continue to require reporting, recordkeeping, and compliance requirements, as described in the Summary above. The requirements of the rules proposed for readoption and the proposed amendments would continue to require the same attendant costs described in the Economic Impact above, if any, to all businesses as they always have. The rules have been developed for the benefit of all children attending schools or preschool facilities in New Jersey. Since prevention of these specific vaccine-preventable diseases is in the public health interest, no differentiation based on business size has been provided in the rules.

N.J.A.C. 8:57-5: The readoption of this subchapter and the addition of new reporting and operational requirements through proposed amendments and new rules, as described in the Summary above, will impose additional reporting, recordkeeping and compliance requirements on some small businesses as defined by the Regulatory Flexibility Act, N.J.S.A. 52:14B-16 et seq. The small

businesses that could potentially be impacted would be health care providers and small specialty clinics managing patients with suspected or confirmed infectious or potentially infectious TB disease. Potential costs to these businesses to meet the reporting, recordkeeping and compliance requirements are described in the Economic Impact above. The application of the proposed requirements universally is essential to prevent TB transmission in the community and safeguard the public health, and therefore no differentiation based on business size is warranted.

N.J.A.C. 8:57-6: A Regulatory Flexibility analysis is not required because the rules proposed for readoption and the proposed amendments and new rules do not impose reporting, record keeping, or other compliance requirements on small businesses, as defined in the Regulatory Flexibility Act, N.J.S.A. 52:14B-16 et seq. Institutions of higher education are not considered small businesses because they employ 100 or more people.

N.J.A.C. 8:57-7: A regulatory flexibility analysis is not required because the rules proposed for readoption do not impose reporting, recordkeeping or other compliance requirements on small businesses as defined under the Regulatory Flexibility Act, N.J.S.A. 52:14B-16 et seq. The rules set forth the requirement that full-time students attending or entering New Jersey colleges and universities have health insurance coverage. Thus, the rules affect student and organizations (colleges and universities) with more than 100 employees and place no

requirements on small businesses, as the term is defined in the Regulatory Flexibility Act.

N.J.A.C. 8:57-8: The rules proposed for readoption with amendments and new rules do not have an impact upon carriers that meet the definition of "small businesses" at N.J.S.A. 52:14B-16 et seq., because carriers located in this State employ 100 or more employees. Therefore, a regulatory flexibility analysis is not required.

N.J.A.C. 8:58: The rules proposed for readoption with amendments at N.J.A.C. 8:58-1.4 would impose requirements only on hospitals licensed in New Jersey, which are not considered to be "small businesses" within the meaning of the Regulatory Flexibility Act, N.J.S.A. 52:14B-16 et seq., as each employs more than 100 full-time employees. Therefore, these rules proposed for readoption with amendments would impose no compliance, reporting, or recordkeeping requirements on small businesses, and no regulatory flexibility analysis is necessary for N.J.A.C. 8:58-1.4.

The rules proposed for readoption with amendments at N.J.A.C. 8:58-1.5 apply to those New Jersey health care providers who are small businesses by virtue of being in solo practice or in group practices of less than 100 full-time employees. Most physicians are in small businesses, as the term is defined in the Regulatory Flexibility Act, N.J.S.A. 52:14B-16 et seq.

The compliance requirements that the rules proposed for readoption at N.J.A.C. 8:58-1.5 have imposed, and would continue to impose, on small

businesses would remain the same as described in the Summary above. The costs to small businesses for compliance with the rules proposed for readoption at N.J.A.C. 8:58-1.5 would remain the same with the exception of costs associated with the proposed amendments, which add reporting of suspect cases work-related asthma, work-related carpal tunnel syndrome, and other occupational diseases as described in the Economic Impact statement above.

Because uniform application of the rules proposed for readoption with amendments is essential for public health purposes with regard to the identification and prevention of occupational and environmental diseases, injuries, and poisonings, the Department has determined that these rules will be applicable to all health care providers without any exceptions.

Proposed Amendments to Other Rules: The Department's proposed amendments to N.J.A.C. 8:36-18.4, 8:39-27.4; 8:43D-15.4, 8:43H-20.2, and 8:52-12.3 are technical to correct citations and therefore, would not have an impact on "small businesses" within the meaning of the Regulatory Flexibility Act, N.J.S.A. 52:14B-16 et seq. pursuant to this rulemaking.

Smart Growth Impact

The rules proposed for readoption with amendments, proposed repeals, proposed amendments and proposed new rules would not have an impact on the achievement of smart growth and implementation of the State Development and Redevelopment Plan.

The Department has provided a 60-day comment period for this notice of proposal; therefore, this notice of proposal is excepted from the rulemaking calendar requirement, pursuant to N.J.A.C. 1:30-3.3(a)5.

Full text of the rules proposed for readoption may be found in the New Jersey Administrative Code at N.J.A.C. 8:57.

Full text of the following rules proposed for repeal may be found in the New Jersey Administrative Code at N.J.A.C. 8:57-5.3 through 5.6, 5.8 and 5.10 through 5.12.

Full text of the additional rules proposed for repeal, proposed amendments and proposed new rules follows (additions indicated in boldface thus; deletions indicated in brackets [thus]):

8:57-1.1 Purpose and scope

(a) [The purpose of this subchapter is to expedite the reporting of certain diseases or outbreaks of disease so that appropriate action can be taken to protect the public health. The latest edition of the American Public Health Association's publication, “Control of Communicable Diseases Manual,” should be used as a reference, providing guidelines for the characteristics and control of communicable diseases, unless other guidelines are issued by the Department.] The rules are designed to promote the identification and reporting of specified communicable diseases so that public health officials can take appropriate action

to prevent the further spread of those diseases to other persons and thereby preserve, maintain, or improve the public health.

(b) [For purposes of research, surveillance, and/or in response to technological developments in disease detection or control, the Commissioner, or his or her designee, is empowered to amend the diseases specified in this subchapter for such periods of time as may be necessary to control disease, in accordance with the Administrative Procedure Act, N.J.S.A. 52:14B-1 et seq.] This subchapter establishes requirements for:

1. Reporting of communicable diseases by physicians, physician assistants, advanced practice nurses, health officers, veterinarians, certified animal control officers, managers of animal facilities, and administrators of health care facilities, correctional facilities, youth camps, child care centers, preschools, schools and institutions of higher education;

2. Reporting of laboratory tests indicative of communicable diseases by clinical laboratory directors; and

3. Specimen submission of isolates of communicable disease organisms by clinical laboratory directors.

(c) This subchapter also covers investigation requirements and regulatory actions to be taken by the local health officer or the Department when notified of a communicable disease; isolation and quarantine restrictions, medical examination and specimen submission requirements that may be placed upon a person ill with a communicable disease; restrictions that may be placed upon a

foodhandler ill or infected with a communicable disease; and requirements for confidentiality and enforcement.

(d) The Commissioner may amend the reportable communicable diseases specified at N.J.A.C. 8:57-1.5, 1.7 and 1.8 for such periods of time as may be necessary to control disease, in accordance with the Administrative Procedure Act, N.J.S.A. 52:14B-1 et seq. for purposes of research, surveillance, and/or in response to technological developments in disease detection or control.

(e) The Commissioner may amend any provision of this chapter during a public health emergency by order of the Commissioner pursuant to the Emergency Health Powers Act, N.J.S.A. 26:13-1 et seq.

1. The Department will provide public notice of any amendment made pursuant to (e) above through the New Jersey Local Information Network and Communications System (NJLINCS).

(f) The Department's Communicable Disease Service is a public health entity with public health oversight functions pursuant to the Health Insurance Portability and Accountability Act of 1996, 45 CFR §§164.501 and 164.512(b), referred to as HIPAA.

8:57-1.2 Incorporated documents

(a) The Department incorporates by reference in this subchapter the Electronic Laboratory Reporting Technical Manual, written and published by the New Jersey Department of Health and Senior Services, Communicable Disease

Service and the Office of Information Technology Services, which provides technical guidance on the electronic transmission of data to the Department.

1. The Electronic Laboratory Reporting Technical Manual is available at Appendix A and by written request to the Communicable Disease Service, New Jersey Department of Health and Senior Services, PO Box 369, Trenton, NJ 08625, or online through the Department's web page at http://www.state.nj.us/health/cd/izdphome.htm.

8:57-[1.2] 1.3 Definitions

The following words and terms, as used in this [subchapter] chapter, shall have the following meanings, unless the context clearly indicates otherwise or another subchapter defines one of the following words or terms differently for the purposes of that subchapter.

"Administrator" shall mean the person having control or supervision over a health care facility, correctional facility, school, youth camp, child care center, preschool, or institution of higher education.

"Animal facility" shall have the meaning established for "facility" at N.J.A.C. 8:23A-1.1.

"Bioterrorism" [means premeditated use of biological agents (bacteria, viruses, etc.) to cause death or disease in humans, animals or crops] shall have the meaning established at N.J.S.A. 26:13-2.

"Certified animal control officer" shall have the meaning established at N.J.A.C. 8:23A-2.1.

"Child care center" [means any home or facility required to be licensed by the Department of Human Services which is maintained for the care, development, or supervision of six or more children under six years of age who attend for less than 24 hours a day] shall have the meaning established at N.J.A.C. 10:122-1.2.

"Clinical laboratory" shall have the meaning established at N.J.S.A. 45:9-42.27.

"Clinical laboratory director" shall have the meaning established at N.J.S.A. 45:9-42.27.

"Commissioner" means the [New Jersey] Commissioner of the New Jersey Department of Health and Senior Services, or his or her designee.

. . .

"Domestic companion animal" shall mean any domestic dog, cat, ferret, bird, reptile, rodent, rabbit not raised for food or fiber, or other animal kept primarily as a household pet for personal appreciation and companionship.

1. Domestic companion animal includes feral and free-roaming dogs and cats.

2. Domestic companion animal does not include:

i. Livestock and aquaculture as defined at N.J.A.C. 2:2-1.1 and regulated by the New Jersey Department of Agriculture, and

ii. Animals regulated under the Animal Welfare Act, 7 U.S.C. §§2131 et seq., and the regulations promulgated thereunder at 9 CFR §§1.1 through 4.11 as research animals.

"Electronic laboratory reporting (ELR)" means submission of laboratory test results through an electronic file to the Department's Office of Information Technology Services' dedicated secure server via Secure File Transfer protocol (SFTP), Virtual Private Network (VPN), or any other secure transmission acceptable to the Department.

1. The format of the electronic file must be one that is specified in the Electronic Laboratory Reporting Technical Manual, available at Appendix A.

2. Further information on transmission protocols, file formats, laboratory coding, test plans to initiate electronic laboratory reporting with the Department and contact information can be found in the Electronic Laboratory Reporting Technical Manual, available at Appendix A.

"Electronic reporting" means submission of [disease/test reports on diskette, as an e-mail attachment, as an FTP (File Transfer Protocol) file, using a mailbox via an Intranet, or using other technologies. Encryption is a prerequisite for electronic reporting, to protect the confidentiality of the data] data via Web entry into the Department's Communicable Disease Reporting and Surveillance System (CDRSS).

1. Information regarding CDRSS is available in the CDRSS Information Guide, which is written and published by the Communicable Disease Service,

New Jersey Department of Health and Senior Services and is available by written request to the Communicable Disease Service, New Jersey Department of Health and Senior Services, PO Box 369, Trenton, NJ 08625-0369 or online through the Department's web page at http://www.state.nj.us/health/cd/index.html

"Ethnicity" means cultural background, [as in] for example Hispanic or Latino.

"Health care facility" shall have the meaning established at N.J.S.A 26:2H-2.

"Health care provider" means a physician, physician assistant, advanced practice nurse or certified nurse midwife licensed pursuant to Title 45 of the New Jersey Revised Statutes.

"Health officer" means a [holder of a license as] person who is licensed as a health officer [issued by the New Jersey Department of Health and Senior Services,] pursuant to N.J.S.A. 26:1A-38 et seq. and N.J.A.C. 8:7-1.1 et seq., [who] and is employed [by a local board of health to function during all working hours of the regularly scheduled work week of the governmental unit to which the local health agency is attached and not regularly employed during the working hours of that scheduled work week in other activities for which he or she receives remuneration] full-time as the chief executive officer of a municipal, regional, county or contractual health agency, or his or her designee.

1. This person is responsible for evaluating health problems, planning appropriate activities to address these health problems, developing necessary

budget procedures to finance these activities, and directing staff to carry out these activities efficiently and economically.

["Health care provider" means a person who is directly involved in the provision of health care services, such as the clinical diagnosis and prescribing of medications, and when required by State law, the individual has received professional training in the provision of such services and is licensed or certified for such provision. This includes physicians, physician assistants, and nurse practitioners.]

"Hospital-onset methicillin-resistant *Staphylococcus aureus* (MRSA) invasive infections" means isolation of MRSA from a normally sterile site, such as blood, cerebro-spinal fluid, or joint, pleural, or pericardial fluid, greater than 48 hours after admission to the hospital.

["Hospital or other health care institution" means an institution, whether operated for profit or not, which maintains and operates facilities for the diagnosis, treatment, or care of two or more non-related individuals suffering from illness, injury or deformity and where emergency, outpatient, surgical, obstetrical, convalescent, or other medical and nursing care is rendered for periods exceeding 24 hours.]

"Influenza virus, novel strain" shall mean a virus subtype that is different from the human influenza A H1 and H3 viruses that have been circulating that influenza season.

. . .

"Isolation" shall have the meaning established at N.J.S.A. 26:13-2.

"Kennel" shall have the meaning established at N.J.A.C. 8:23A-1.1.

. . .

"Methicillin-resistant *Staphylococcus aureus* (MRSA)" means any *Staphylococcus aureus* isolate with resistance to oxacillin or methicillin, detected and defined according to the Performance Standards for Antimicrobial Susceptibility Testing; Seventeenth Informational Supplement (M100-S17), which is written and published by the Clinical and Laboratory Standards Institute and is available for a fee from the Clinical and Laboratory Standards Institute, 940 West Valley Road, Suite 1400, Wayne, PA 19087, or online at http://www.clsi.org.

"Multidrug-resistant organisms" or "MDROs" means bacteria (excluding *Mycobacterium tuberculosis*) that are resistant to one or more classes of antimicrobial agents and usually are resistant to all but one or two commercially available antimicrobial agents (for example, MRSA, vancomycin resistant enterococcus (VRE), extended spectrum beta-lactamase (ESBL)-producing or intrinsically resistant gram-negative bacilli).

"Neonatal" shall mean a child less than 90 days of age.

["N.J.A.C." means the New Jersey Administrative Code.

"N.J.S.A." means the New Jersey Statutes Annotated.]

"Nosocomial infection" means an infection occurring in a patient in a [hospital or other]health care facility and in whom it was not present or

incubating at the time of admission, or the residual of an infection acquired during a previous admission.

1. This term includes infections acquired in the [hospital] health care facility but appearing after discharge, and also such infections among the staff of the facility.

"Outbreak" means any unusual occurrence of disease or any disease above background or endemic levels.

1. "Endemic level" [refers to] means the usual prevalence of a given disease within a geographic area.

2. "Suspected outbreak" means an outbreak, which appears to meet the definition of an outbreak, but has not yet been confirmed.

"Overlap agent or toxin" shall have the meaning established at N.J.S.A. 26:13-2.

"Pediatric" means a person who has not yet attained the age of 18 years.

"Pet shop" shall have the meaning established at N.J.A.C. 8:23A-1.1.

"Pound" shall have the meaning established at N.J.A.C. 8:23A-1.1.

"Public health emergency" shall have the meaning established at N.J.S.A. 26:13-2.

"Quarantine" shall have the meaning established at N.J.S.A. 26:13-2.

. . .

"Shelter" shall have the meaning established at N.J.A.C. 8:23A-1.1.

"Vancomycin-intermediate Staphylococcus aureus (VISA)" and "Vancomycin-resistant Staphylococcus aureus (VRSA)" mean any *Staphylococcus aureus* isolate with intermediate susceptibility or resistance to vancomycin, detected and defined according to Clinical and Laboratory Standards Institute's Performance Standards for Antimicrobial Susceptibility Testing; Seventeenth Informational Supplement (M100-S17).

"Veterinarian" shall mean a person licensed by the State Board of Veterinary Medical Examiners to engage in the practice of veterinary medicine, surgery and dentistry, pursuant to N.J.A.C. 13:44-1.1 et seq.

"Zoonotic disease" shall mean a communicable disease transmissible from vertebrate animals to humans, and may include transmission by intermediate vectors such as mosquitoes or ticks.

8:57-1.4 [Persons and institutions required to report] Health care provider and administrator reporting of reportable communicable diseases

(a) [The following individuals and institutions are required to] Every health care provider and administrator shall report any person who is ill or infected with any disease listed in N.J.A.C. [8:57-1.3] 8:57-1.5 within the required timeframe, and shall make a report as set forth in N.J.A.C. [8:57-1.5:] 8:57-1.6.

[1. Physician;

2. Advanced practice nurse;

3. Physician's assistant; or

4. A person having control or supervision over a hospital or other health care institution, correctional facility, school, summer camp, child care center, preschool, or institution of higher education.]

(b) Duplicate reporting of the same case by [health care providers in the same institution] health care providers and administrators is not necessary.

(c) [A physician, advanced practice nurse, physician's assistant, or a person having control or supervision over a hospital or other health care institution, correctional facility, school, summer camp, child care center, preschool, or institution of higher education who fails to report pursuant to the provisions of N.J.A.C. 8:57-1.3 and 1.5 may receive written notification of this failure and a warning. Responsible parties who, despite warning, continue to fail to comply with these reporting requirements, shall be subject to a fine, pursuant to the provisions of N.J.S.A. 26:4-129. If failure to report is determined by the Department to have significantly hindered public health control measures, the responsible parties shall be subject to other actions, including, but not limited to, notification of the violation to relevant licensing review organizations.] Health care providers and administrators may delegate these reporting requirements to a member of the staff, but this delegation does not relieve the health care provider or administrator of the ultimate reporting responsibility.

8:57-[1.3] 1.5 Reportable communicable diseases

(a) [Cases due to the following diseases and/or infectious agents shall be reported. Diseases in List 1 shall include confirmed and suspect cases and shall be reported immediately by telephone. Diseases in List 2 shall include confirmed cases and shall be reported within 24 hours of diagnosis.

1. List of immediately reportable diseases] Health care providers and administrators shall immediately report by telephone as set forth at N.J.A.C. 8:57-1.6 confirmed and suspected cases of the following reportable communicable diseases:

Anthrax (*Bacillus anthracis*);

Botulism (*Clostridium botulinum*);

Brucellosis (*Brucella* spp.);

Diphtheria (*Corynebacterium diphtheriae*);

Foodborne intoxications, including, but not limited to, ciguatera, paralytic shellfish poisoning, scombroid, or mushroom poisoning;

Haemophilus influenzae, invasive disease;

Hantavirus [infection] pulmonary syndrome;

Hepatitis A, acute [in institutional settings];

Influenza, novel strains only;

Measles (*Rubeola* virus);

Meningococcal invasive disease (*Neisseria meningitidis*);

Outbreak or suspected outbreak of illness, including, but not limited to, foodborne, waterborne or nosocomial disease or a suspected act of bioterrorism;

Pertussis [whooping cough], (*Bordetella pertussis*);

Plague (*Yersinia pestis*);

Rubella;

Poliomyelitis;

Rabies (human illness);

SARS-CoV Disease (SARS);

Smallpox;

Tularemia (*Francisella tularensis*); and

Viral hemorrhagic fevers, including, but not limited to, Ebola, Lassa, and Marburg viruses.[;

Foodborne intoxications, including, but not limited to, ciguatera, paralytic shellfish poisoning, scombroid, or mushroom poisoning;

Any outbreak or suspected outbreak, including, but not limited to, foodborne, waterborne or nosocomial disease or a suspected act of bioterrorism;

2. List of diseases reportable within 24 hours of diagnosis]

(b) Health care providers and administrators shall report within 24 hours of diagnosis as set forth at N.J.A.C. 8:57-1.6 confirmed cases of the following reportable communicable diseases:

Amoebiasis (*Entamoeba histolytica*);

Animal bites treated for rabies;

Arboviral diseases;

Babesiosis (*Babesia* spp.);

Campylobacteriosis (*Campylobacter* spp.);

Chancroid (*Haemophilus ducreyi*);

Chlamydial infections, sexually transmitted (*Chlamydia trachomatis*);

Chlamydial conjunctivitis, neonatal (*Chlamydia trachomatis*);

Cholera (*Vibrio cholerae*);

Creutzfeld-Jakob disease;

Cryptosporidiosis (*Cryptosporidium* spp.);

Cyclosporiasis (*Cyclospora* spp.);

[Dengue fever;]

Diarrheal disease, either in a child who attends a day care center or in a foodhandler;

Ehrlichiosis (*Ehrlichia* spp.);

[Enterohemorrhagic] *Escherichia coli*, shiga toxin producing strains (STEC) only;

Giardiasis (*Giardia lamblia*);

Gonorrhea (*Neisseria gonorrhoeae*);

Granuloma inguinale ([*Calymmatobacterium*] *Klebsiella granulomatis*);

[Guillain-Barre syndrome;]

Hansen's disease (*Mycobacterium leprae*);

Hemolytic uremic syndrome, post-diarrheal;

[Hepatitis A;]

Hepatitis B, [including] newly diagnosed acute, perinatal and chronic infections, and pregnant women who have tested positive for Hepatitis B surface antigen [test positive in a pregnant woman];

Hepatitis C, acute and chronic, newly diagnosed cases only;

Influenza-associated pediatric mortality;

[Kawasaki disease (mucocutaneous lymph node syndrome);]

Legionellosis [(*Legionella pneumophila*)] (*Legionella spp.*);

Listeriosis (*Listeria monocytogenes*);

Lyme disease (*Borrelia burgdorferi*);

Lymphogranuloma venereum (*Chlamydia trachomatis*);

Malaria (*Plasmodium* spp.);

Mumps;

Psittacosis (*Chlamydia psittaci*);

Q fever (*Coxiella burnetti*);

Rocky Mountain Spotted Fever (*Rickettsia rickettsii*);

Rubella, congenital;

Salmonellosis (*Salmonella* spp.);

Shigellosis (*Shigella* spp.);

Staphylococcus aureus, with intermediate- (VISA) or high-level-resistance (VRSA) to vancomycin only;

Streptococcal disease, invasive group A, (*Streptococcus pyogenes* group A);

Streptococcal disease, invasive group B, neonatal;

Streptococcal toxic-shock syndrome;

Streptococcus pneumoniae, invasive disease;

Syphilis, all stages [primary, and secondary] (*Treponema pallidum*);

Syphilis, congenital;

Tetanus (*Clostridium tetani*);

Toxic Shock syndrome (other than Streptococcal);

[Trichinosis] Trichinellosis (*Trichinella spiralis*);

Tuberculosis, confirmed or suspect (*Mycobacterium tuberculosis*) (additional reporting requirements set forth at N.J.A.C. 8:57-5.3);

Typhoid fever (*Salmonella typhi*);

Varicella (chickenpox);

[Vibrio infections other than cholera (*Vibrio* spp.)] Vibriosis;

Viral encephalitis;

Yellow fever (Flavivirus); and

Yersiniosis (*Yersinia* spp.).

(c) Health care providers and administrators shall immediately report to the Department by telephone as set forth at N.J.A.C. 8:57-1.6 any disease or

health condition that may reasonably be a potential case of a public health emergency as set forth at N.J.S.A. 26:13-4.

(d) An administrator of a general hospital licensed by the Department in accordance with N.J.S.A. 26:2H-1 et seq. and as classified in the Hospital Licensing Standards at N.J.A.C. 8:43G-1.2 and 1.3(b) shall, within 30 calendar days of the end of each month, submit to the Department:

1. The number of cases of hospital-onset MRSA bloodstream infections per 1000 patient days that have occurred in his or her general hospital, specified by hospital unit where active surveillance testing for MRSA is being performed, and

2. The percentage of eligible patients who have a MRSA surveillance test performed on admission to a hospital unit where active surveillance testing for MRSA is being performed.

i. The administrator shall submit the information set forth in (d)1 and 2 above using a web-based interface to be developed and communicated by the Department.

[(b)] (e) Reporting of Acquired Immunodeficiency Syndrome (AIDS) and infection with Human Immunodeficiency Virus (HIV) shall be in the manner [described in] set forth at N.J.A.C. 8:57-2.

8:57- [1.5] 1.6 Method of reporting and [Content] content of report

(a) [Any individual with a disease listed in N.J.A.C. 8:57-1.3 shall be reported as set forth in (c) and (d) below] Health care providers and administrators shall immediately report by telephone the information set forth at (c) and (d) below on confirmed and suspected cases of immediately reportable communicable diseases set forth in N.J.A.C. 8:57-1.5(a) to the health officer of the jurisdiction where the [individual] ill or infected person lives, or if unknown, wherein the diagnosis is made, except that health care providers and administrators shall report [individuals with hepatitis C, sexually transmitted diseases and tuberculosis and all individuals] ill or infected persons in State owned institutions, such as State correctional facilities, [shall be reported] directly to the Department.

1. If the health officer is unavailable, the [report shall be made] health care provider or administrator shall make the report to the Department by telephone to [(]609-588-7500, between 8:00 A.M. and 5:00 P.M. on non-holiday weekdays [during business hours;] or to 609-392-2020 during all other days and hours[, after business hours, on weekends and holidays)].

2. Health care providers and administrators may use the Directory of Local Health Departments in New Jersey to locate health officers and local health departments in New Jersey.

i. The Directory of Local Health Departments in New Jersey is written and published by the New Jersey Department of Health and Senior Services, Office of Public Health Infrastructure and is available by written request to the Office of

Public Health Infrastructure, New Jersey Department of Health and Senior Services, PO Box 360, Trenton, NJ 08625-0360 or online through the Department's web page at http://www.state.nj.us/health/lh/lhdirectory.pdf.

(b) [Any outbreak or suspected outbreak listed in N.J.A.C. 8:57-1.3 shall be reported as set forth in (e) and (f) below to the health officer of the jurisdiction where the outbreak occurred. If the health officer is unavailable, the report shall be made to the Department by telephone (609-588-7500, during business hours; 609-392-2020, after business hours, on weekends and holidays)] Health care providers and administrators shall report by mail or by electronic reporting within 24 hours of diagnosis, the information set forth at subsection (c) below on confirmed cases of reportable communicable diseases set forth in N.J.A.C. 8:57-1.5(b) to the health officer of the jurisdiction where the ill or infected person lives, or if unknown, wherein the diagnosis is made, except that health care providers and administrators shall report persons with hepatitis C, sexually transmitted diseases and tuberculosis and all persons in State owned institutions, such as State correctional facilities, directly to the Department.

1. If the health officer is unavailable, the health care provider or administrator shall make the report to the Department by telephone to 609-588-7500, between 8:00 A.M. and 5:00 P.M. on non-holiday weekdays or to 609-392-2020 during all other days and hours.

2. Health care providers and administrators may use the Directory of Local Health Departments in New Jersey to locate health officers and local health departments in New Jersey.

3. Health care providers and administrators may mail reports to the Department at the following address: Communicable Disease Service, New Jersey Department of Health and Senior Services, PO Box 369, Trenton, NJ 08625-0369.

[(c) Individuals with diseases in N.J.A.C. 8:57-1.3(a)1 shall be reported immediately by telephone. All individuals with diseases in N.J.A.C. 8:57- 1.3(a), including those reported immediately by telephone, shall be reported in writing or as an electronic report within 24 hours of diagnosis.]

[(d)] (c) The disease report set forth at (a) and (b) above shall include:

1. The name of the disease;

2. The name, age, date of birth, gender, race, ethnicity, home address and telephone number of the person who is ill or infected with such disease;

3. The date of onset of illness;

4. The name, address, institution, and telephone number of the reporting [official; and] health care provider or administrator;

5. Clinical laboratory data, which support the diagnosis;

6. Any treatment provided (for sexually transmitted diseases only); and

[5] 7. Such other information as the Department requires [may be required by the Department] concerning a specific disease.

[(e) All outbreaks shall be reported immediately by telephone.]

[(f)] (d) [Outbreak] In addition to the information set forth at (c) above, outbreak reports shall include:

1. The name, municipality, and telephone number of the [institution or school] location where the outbreak occurred;

[2. The name of the disease or suspected disease;]

[3] 2.The number ill;

[4. The dates of onset;]

[5] 3. A description of symptoms; and

[6] 4. Pertinent medical history and available diagnostic [confirmation] information; and

[7] 5. Such other information as may be requested by the health officer or the Department concerning a specific disease.

[(g) The person having control or supervision of an institution may delegate these reporting activities to a member of the staff, but this delegation does not relieve that person of the ultimate reporting responsibility].

(e) Health care providers and administrators shall immediately report to the Department all cases of persons who harbor or are suspected of harboring any illness or health condition that may be reasonably believed to be a potential cause of a public health emergency as set forth in the Emergency Health Powers Act, N.J.S.A. 26:13-4.

1. Health care providers and administrators shall make reports to the Department by telephone to 609-588-7500, between 8:00 A.M. and 5:00 P.M. on non-holiday weekdays or to 609-392-2020 during all other days and hours.

8:57- [1.6] 1.7 Reporting of positive laboratory results denoting diseases

(a) A clinical laboratory director shall immediately report by telephone the information set forth at (c) below on any positive culture, test, or assay result specific for the following organisms to the local health officer:

Arboviruses;

Bacillus anthracis;

Bordetella pertussis;

Brucella spp.;

Clostridium botulinum;

Corynebacterium diphtheriae;

Ebola virus;

Foodborne intoxications, including, but not limited to, ciguatera, paralytic shellfish poisoning, scombroid, or mushroom poisoning;

Francisella tularensis;

Haemophilus influenzae isolated from cerebrospinal fluid, blood, or any other normally sterile body site;

Hantavirus;

Hepatitis A, (IgM tests only);

Influenza virus, novel strains only;

Lassa virus;

Marburg virus;

Neisseria meningitidis isolated from cerebrospinal fluid, blood, or any other normally sterile site;

Polio virus;

Rabies virus;

Rubella virus;

SARS-CoV; and

Yersinia pestis.

1. If the health officer is unavailable, the clinical laboratory director shall make the report to the Department by telephone to 609-588-7500, between 8:00 A.M. and 5:00 P.M. on non-holiday weekdays or to 609-392-2020 during all other days and hours.

2. In addition to the telephone report, the clinical laboratory director shall report the information set forth at (c) below by electronic reporting, by electronic laboratory reporting or by mail within 72 hours of obtaining the result.

i. The clinical laboratory director may use the Directory of Local Health Departments in New Jersey to locate health officers and local health departments in New Jersey.

3. Effective September 1, 2010, in addition to the telephone report, the clinical laboratory director shall report the information set forth at subsection (c) through electronic laboratory reporting within 24 hours of obtaining the result.

i. The clinical laboratory director may substitute electronic reporting if electronic laboratory reporting is not available.

ii. The clinical laboratory director may substitute reporting by mail upon approval of the Department for equipment failure or other circumstances, which prevent electronic communications with the Department.

iii. Clinical laboratory directors shall utilize the Electronic Laboratory Reporting Technical Manual available at Appendix A to establish electronic laboratory reporting.

[(a)] (b) A clinical laboratory director shall report by electronic laboratory reporting, by electronic reporting, or by mail within 72 hours of obtaining the result the information set forth at subsection (c) below on [Any] any positive culture, test, or assay result specific for one of the following organisms [shall be reported by a laboratory director] to the local health [department] officer of the jurisdiction where the person lives, or if unknown, to the local health officer in whose jurisdiction the health care provider or health care facility requesting the laboratory examination is located, except that the clinical laboratory director shall report positive results for hepatitis C, tuberculosis and sexually transmitted diseases [shall be reported] directly to the Department:

[1.] Acid fast bacilli;

[2.] Antibiotic-resistant organisms (hospital-based laboratories only);

[3. *Arboviruses;]

[4.] *Babesia* spp.;

[5. *Bacillus anthracis;]

[6. *Bordetella pertussis;]

[7.] *Borrelia burgdorferi*;

[8. *Brucella spp.;]

[9.] *Campylobacter* spp.;

[10.] *Chlamydia psittaci*;

[11.] *Chlamydia trachomatis*;

[12. *Clostridium botulinum;]

[13.] Clostridium tetani;

[14. *Corynebacterium diphtheriae;]

[15.] *Coxiella burnetti*;

[16.] *Cryptosporidium* spp.;

[17.] *Cyclospora* spp;

[18. *Ebola virus;]

[19.] *Entamoeba histolytica*;

[20.] *Ehrlichia* spp.;

[21.] *Escherichia coli*, shiga toxin producing strains (STEC) only [0157: H7 and other hemorrhagic strains];

[22. *Foodborne intoxications, including, but not limited to, ciguatera, paralytic shellfish poisoning, scombroid, or mushroom poisoning;]

[23. *Francisella tularensis;]

[24.] *Giardia lamblia*;

[25. *Hantavirus;]

[26.] *Haemophilus ducreyi*;

[27. *Haemophilus influenzae* isolated from cerebrospinal fluid, blood, or any other normally sterile body site;]

[28. Hepatitis A;]

[29.] Hepatitis B;

[30.] Hepatitis C;

Influenza, all isolates (only for laboratories reporting electronically, or by electronic laboratory reporting);

Klebsiella granulomatis;

[31. *Lassa virus;]

[32. *Legionella pneumophila*] *Legionella spp.*;

[33.] *Listeria monocytogenes*;

[34. *Marburg virus;]

[35.] Mumps virus;

[36.] *Mycobacterium*, atypical;

[37.] *Mycobacterium leprae*;

[38.] *Mycobacterium tuberculosis*, including antibiotic sensitivity tests for *M. tuberculosis*;

[39.] *Neisseria gonorrhoeae*;

[40. *Neisseria meningitidis* isolated from cerebrospinal fluid, blood, or any other normally sterile site;]

[41.] *Plasmodium* spp.;

[42. Polio virus;]

[43. *Rabies virus;]

[44.] *Rickettsia rickettsii*;

[45. *Rubella virus;]

[46.] Rubeola virus;

[47.] *Salmonella* spp.;

[48.] *Shigella* spp.;

Staphylococcus aureus, with intermediate- (VISA) or high-level-resistance (VRSA) to vancomycin only;

[49.] *Streptococcus pneumoniae* isolated from cerebrospinal fluid, blood, or any other normally sterile site, and antimicrobial susceptibility test results, if performed;

[50.] *Streptococcus pyogenes*, Group A, isolated from cerebrospinal fluid, blood, or other normally sterile site;

[51.] *Streptococcus agalactiae*, Group B, [perinatal] neonatal;

[52.] *Treponema pallidum*;

[53.] *Trichinella spiralis*;

Varicella virus (except IgG tests);

[54.] *Vibrio* spp.; and

[55.] *Yersinia* spp.[;]

[56. *Yersinia pestis; and

57. Antibiotic sensitivity for M. tuberculosis.]

1. The clinical laboratory director may use the Directory of Local Health Departments in New Jersey to locate health officers and local health departments in New Jersey.

2. The Clinical laboratory director may mail reports to the Department at the following address: Communicable Disease Service, New Jersey Department of Health and Senior Services, PO Box 369, Trenton, NJ 08625-0369.

3. Effective September 1, 2010, the clinical laboratory director shall report the information set forth at (c) by electronic laboratory reporting within 24 hours of obtaining the result.

i. The clinical laboratory director may substitute electronic reporting if electronic laboratory reporting is not available.

ii. The clinical laboratory director may substitute reporting by mail upon approval of the Department for equipment failure or other circumstances, which prevent electronic communications with the Department.

iii. Clinical laboratory directors shall utilize the Electronic Laboratory Reporting Technical Manual, available at Appendix A, to establish electronic laboratory reporting.

[(b) A laboratory director shall report positive cultures or positive laboratory test results for the microorganisms listed in (a) above within 72 hours after obtaining a positive result, except that positive cultures or positive laboratory test results for the microorganisms noted by an asterisk (*) shall be reported

immediately by telephone. All reports shall be submitted to the health officer having jurisdiction over the locality in which the patient lives, or, if unknown, to the health officer in whose jurisdiction the health care provider requesting the laboratory examination is located, except that reports of organisms for hepatitis C, tuberculosis and sexually transmitted diseases and all reports where the patient is a resident of a State institution shall be submitted directly to the Department. If the health officer is unavailable, the report shall be made to the Department by telephone (609-588-7500, during business hours; 609-392-2020, after business hours, on weekends and holidays).]

(c) The report shall contain [, at a minimum,] the reporting laboratory's name, address, and telephone number; the name, age, date of birth, gender, race, ethnicity, home address and telephone number of the person tested; the test performed; the source or type of specimen tested, the date the specimen was collected, the date of testing; the test results; and the health care provider's name, [and] address, and telephone number.

(d) A clinical laboratory director may delegate reporting and specimen submission requirements [activities], as delineated in (a) and (b) above, and [(f)] (e) below, to a staff member, but this delegation does not relieve [a] the clinical laboratory director of the ultimate reporting responsibility.

[(e) A laboratory director who fails to fulfill the reporting requirements and the specimen submission requirements of this section may receive written notification of this failure and a warning to comply. A laboratory director who,

despite warning, continues to fail to comply with these reporting requirements, shall be subject to a fine pursuant to the provisions of N.J.S.A. 26:4-129. A laboratory director whose failure to report is determined by the Department to have significantly hindered public health control measures shall be subject to other actions, including, but not limited to, reporting such failure to the Department's Clinical Laboratory Improvement Services.]

[(f)] (e) A clinical laboratory director shall submit within three days of identification, to the New Jersey Department of Health and Senior Services, Division of Public Health and Environmental Laboratories, John Fitch Plaza, Market and Warren Streets, Trenton, NJ 08625-0361, [for further testing,] all microbiologic culture[s] isolates obtained from human or food specimens of the following organisms:

[1.] Escherichia coli 0157:H7 and enrichment broths containing shiga-toxin producing E. coli;

[2.] Haemophilus influenzae isolated from cerebrospinal fluid or blood;

[3.] Legionella pneumophila;

[4.] Listeria monocytogenes;

[5.] Neisseria meningitidis;

[6.] Salmonella spp.;

[7.] Shigella spp.;

[8. Streptococcus pyogenes isolated from cerebrospinal fluid, blood, or other normally sterile site;

9. Penicillin-resistant Streptococcus pneumoniae isolated from cerebrospinal fluid, blood, or other normally sterile site;

10. Vancomycin-resistant Enterococcus spp. isolated from cerebrospinal fluid, blood, or other normally sterile site;

11. Glycopeptide resistant Staphylococcus spp. and Streptococcus spp. isolated from any body site; and

12. Multiple antibiotic resistant bacteria (upon request).]

Vancomycin-intermediate Staphylcoccus aureus (VISA) and vancomycin-resistant Staphylococcus aureus (VRSA) from any body site; and

Multidrug-resistant organisms upon the request of the Department.

(f). A clinical laboratory director shall submit all initial Tuberculosis isolates to the Public Health and Environmental Laboratories or a designated entity for the purpose of universal genotyping.

(g) [A hospital laboratory director shall, within 31 calendar days of the end of each month, submit data regarding specific microorganisms occurring during that month within the hospital to the Department, utilizing the Department's Epidemiology Surveillance Form.] A clinical laboratory director for a clinical laboratory performing culture and sensitivity testing on isolates from human specimens shall annually report a cumulative summary of these results to the Department.

1. Each clinical laboratory director shall:

i. Submit the data in the format of antibiograms as defined by Analysis and Presentation of Cumulative Antimicrobial Susceptibility Test Data, Approved Guideline – Second Edition (M39-A2), which is written and published by the Clinical and Laboratory Standards Institute and is available for a fee from the Clinical and Laboratory Standards Institute, 940 West Valley Road, Suite 1400, Wayne, PA 19087, or online at http://www.clsi.org;

ii. Include only data from the first unique isolate from each patient;

iii. Exclude duplicate cultures when compiling these antibiograms; and

iv. Send the antibiograms for the preceding year to the Communicable Disease Service, New Jersey Department of Health and Senior Services, PO Box 369, Trenton, NJ 08625-0369 by July 1 of the following year (for example, data for January 1, 2006 through December 31, 2006 is due on July 1, 2007).

(h) A clinical laboratory director who sends a laboratory specimen to a referral laboratory for testing shall be responsible for:

1. Reporting to the Department any test result on that specimen as required under (a) and (b) above; and

2. Submitting to the Department any culture isolate from that specimen as required under (g) above.

i. A clinical laboratory director may delegate the reporting and specimen submission requirements in this subsection to the referral laboratory, but this delegation does not relieve the clinical laboratory director of the ultimate reporting and submitting responsibility.

8:57-1.8 Reporting of zoonotic diseases and any disease outbreaks in domestic companion animals by veterinarians, certified animal control officers, and animal facility management

(a) A veterinarian, certified animal control officer or manager of an animal facility shall report any case of a domestic companion animal that is ill or infected with the following zoonotic diseases, as set forth in (d) and (e) below:

Anthrax (*Bacillus anthracis*);

Avian Chlamydiosis (*Chlamydophila psittaci*);

Brucella canis;

Campylobacteriosis *Campylobacter* spp.);

Escherichia coli shiga toxin producing strains (STEC) only;

Giardia lamblia (oocyst positive only);

Leishmaniasis;

Leptospirosis;

Lymphocytic choriomeningitis;

Mycobacterium tuberculosis;

Plague (*Yersinia pestis*);

Q Fever (*Coxiella burnetti*);

Salmonellosis (*Salmonella* spp.); and

Tularemia (Francisella tularensis).

(b) A veterinarian, certified animal control officer or manager of an animal facility shall report an animal affected with rabies or suspected of being affected with rabies in the manner set forth at N.J.A.C. 8:23-1.2.

(c) A veterinarian, certified animal control officer, or manager of an animal facility shall report any outbreak or suspected outbreak occurring in domestic companion animals as set forth in (d) and (e) below.

(d) A veterinarian, certified animal control officer, or animal facility manager providing care for any domestic companion animal which is ill or infected with any disease listed in (a) above or any outbreak as stated in (c) above, shall within 24 hours of diagnosis or the next working day after diagnosis make a report via mail, telephone, telefacsimile, or electronic reporting as set forth in (e) below to the health officer having jurisdiction over the locality in which the animal or animal facility is located.

1. If the health officer is unavailable, the veterinarian, certified animal control officer, or animal facility manager shall make the report to the Department by telephone to 609-588-3121, between 8:00 A.M. and 5:00 P.M. on non-holiday weekdays.

2. Veterinarians, certified animal control officers, and animal facility managers may use the Directory of Local Health Departments in New Jersey to locate health officers and local health departments in New Jersey.

(e) The report shall include the name, address and telephone number of the animal owner, if the animal is owned; the name, address and telephone number of

the animal facility, if the animal is housed in an animal facility; the name of the disease or suspected disease; the number of animals housed on the premises; the species of animal(s) housed on the premises; the species and number that are ill; date of onset; date purchased or acquired and origin of animals; symptomology; pertinent medical history, and diagnostic test results.

(f) Animal facility staff shall immediately report any suspected zoonotic disease or suspected outbreak of any illness in animals currently or recently housed at that animal facility to the veterinarian responsible for disease control at that animal facility.

(g) A veterinarian, certified animal control officer or animal facility manager may delegate the reporting activities set forth at (d) and (e) above to a member of the staff, but this delegation does not relieve the veterinarian, certified animal control officer, or animal facility manager of the ultimate reporting responsibility.

(h) The Department shall notify the Department of Environmental Protection or Secretary of Agriculture of any report made pursuant to this subchapter, where the Commissioner suspects or detects conditions that could potentially affect animals, plants or crops under the jurisdiction of the Department of Environmental Protection or Department of Agriculture.

8:57- [1.7] 1.9 Reporting of diseases by health officers

(a) A health officer who is notified of the existence of any disease [outbreak, or of any single case of a disease listed in N.J.A.C. 8:57-1.3(a)1,] or illness listed in N.J.A.C. 8:57-1.5(a) or laboratory report listed in N.J.A.C. 8:57-1.7(a) shall immediately notify the Department by telephone to [(]609-588-7500, [during business hours;] between 8:00 A.M. and 5:00 P.M. on non-holiday weekdays or to 609-392-2020 [, after business hours, on weekends and holidays)] during all other days and hours.

(b) A health officer who is notified of the existence of [diseases pursuant to the provisions of N.J.A.C. 8:57-1.3 and 1.6] any disease or illness listed in N.J.A.C. 8:57-1.5 or laboratory report listed in N.J.A.C. 8:57-1.7 shall, within 24 hours of receipt of the report, forward [a written or electronic copy thereof] the information to the Department via electronic reporting.

1. If the initial report is incomplete, [a] the health officer shall seek complete information and shall provide all available information to the Department within five working days of receiving the initial report.

2. The health officer may substitute reporting by mail upon approval of the Department for equipment failure or other circumstances, which prevent electronic communications with the Department.

(c) A health officer who is notified [of any outbreak of disease, or of any single case of a disease listed in N.J.A.C. 8:57-1.3 and 1.6,] of the existence of any disease or illness listed in N.J.A.C. 8:57-1.5 or laboratory report listed in N.J.A.C. 8:57-1.7 which is not within that health officer's jurisdiction shall

immediately notify the health officer in whose jurisdiction [where] the disease or illness [was] is believed to have been contracted and the health officer [of the local health agency wherein] in whose jurisdiction the home address of the ill or affected person is located [, as the case may be].

1. If either of the [said health agencies] above health jurisdictions are not located in New Jersey, the health officer shall forward this information to the Department by telephone to [(]609-588-7500, [during business hours;] between 8:00 A.M. and 5:00 P.M. on non-holiday weekdays or to 609-392-2020 [, after business hours, on weekends, and holidays)] during all other days and hours.

(d) A health officer may delegate reporting [activities] requirements to a staff member, but this delegation shall not relieve the health officer of the ultimate reporting responsibility.

[(e) A health officer who fails to report pursuant to the provisions of this section shall receive written notification of this failure and a warning. A health officer who, despite warning, fails to comply with these reporting requirements, shall be subject to a fine pursuant to the provisions of N.J.S.A. 26:4-129. A health officer whose failure to report is determined by the Department to have significantly hindered public health control measures shall be subject to other actions, including notification to the Department's Public Health Licensing and Examination Board and the Public Health Council.]

8:57- [1.8] 1.10 Health officer investigations

(a) A health officer [shall], upon receiving a report of [an] a reportable communicable disease or outbreak [or suspected outbreak of any communicable disease, or of a case or suspected case of any communicable disease], shall investigate the facts contained in the report. [A health officer shall follow such direction regarding the investigation as may be given by the Department].

1. The health officer may use the Control of Communicable Diseases Manual, 18th Edition, which provides guidelines for the characteristics and control of communicable diseases, unless the Department issues other guidelines.

i. The Control of Communicable Disease Manual, 18th Edition, edited by David L. Heymann, M.D., is available from the American Public Health Association, 800 I Street NW, Washington, DC, 20001, telephone (202) 777-2742.

(b) A health officer shall follow direction given by the Department regarding the investigation set forth in (a) above.

[(b)] (c) The health officer performing the investigation set forth in (a) above shall [, at a minimum]:

1. Determine whether a single case or an outbreak of a reportable communicable disease exists;
2. Ascertain the source and spread of the [infection] illness; and
3. Determine and implement appropriate control measures.

[(c)] (d) Upon determining that a single case of an immediately reportable communicable disease or an outbreak of a reportable communicable disease

exists, the health officer shall immediately relay all available information pertaining to the investigation to the Department by telephone to [(]609-588-7500 [, during business hours;] between 8:00 A.M. and 5:00 P.M. on non-holiday weekdays or to 609-392-2020 [, after business hours, on weekends, and holidays)] during all other days and hours.

1. The health officer shall follow telephone reports of immediately reportable communicable diseases and outbreaks with electronic reporting within 24 hours.

2. Reports of investigations of other reportable communicable diseases [may] shall be submitted [electronically] via electronic reporting, except that sexually transmitted diseases and tuberculosis reports shall be submitted [or] in writing.

[(d)] (e) The Department may require more than one health officer to participate in the investigation [. The] , including the health officers [may include those having] who have jurisdiction over:

1. The location of suspected transmission of disease;
2. Areas of residence or occupation of person(s) believed to be ill or infected;
3. Sites [of institutions] where such persons may be located or [receive] receiving care; and
4. Other jurisdictions which the Department determines are [determined to be] appropriate and necessary[by the Department].

(f) If the Department determines that an outbreak is occurring in more than one jurisdiction, the Department shall coordinate the investigation, in conjunction with the affected health departments, and the Centers for Disease Control and Prevention, as needed.

[(e)] (f) The health officer shall submit a summary report to the Department within 30 days of the completion of each outbreak investigation, and to all physicians who reported cases of illness connected with that outbreak.

1. The report shall include, but not be limited to, a summary of findings, actions taken to control disease, and recommendations to affected parties.

(g) Health officers shall establish quarantine, test and transport procedures for pet birds infected with, or exposed to, avian chlamydiosis in the manner set forth at N.J.A.C. 8:23-1.4.

(h) The Commissioner shall exercise his or her jurisdiction, responsibility and authority during a public health emergency pursuant to N.J.S.A. 26:13-3(c).

8:57- [1.9] 1.11 Isolation and quarantine [restriction] for communicable disease

(a) A health officer or the Department, upon receiving a report of a communicable disease, shall, by written order, establish such isolation or quarantine [other restrictive] measures as medically and epidemiologically necessary [required by statute or rule] to prevent or control the spread of the disease.

1. If, in the medical and epidemiologic judgment of the health officer or the Department, it is necessary to hospitalize the ill person in order to provide adequate isolation, a health officer or the Department shall promptly remove, or cause to be removed, that person [a person who is ill with a communicable disease] to a hospital.

2. Such order shall remain in force until terminated by the health officer or the Department.

3. A health officer may use Quarantine and Isolation – Model Rules for Local Boards of Health, available at Appendix B, as a guide for establishing isolation and quarantine measures.

i. Quarantine and Isolation – Model Rules for Local Boards of Health, is written and published by the Communicable Disease Service, New Jersey Department of Health and Senior Services, and is available at Appendix B, and by written request to the Communicable Disease Service, New Jersey Department of Health and Senior Services, PO Box 369, Trenton, NJ 08625-0369, or online through the Department's web page at http://www.state.nj.us/health/cd/index.html;

(b) A health officer or the Department may restrict access of the persons [individuals] permitted to come in contact with or visit a person who is hospitalized or isolated pursuant to [under authority of] this section where medically or epidemiologically necessary to prevent the spread of the disease.

(c) The Department or health officer [, if authorized by local ordinance or by the Department,] may, by written order, isolate or quarantine [restrict] any person who has been exposed to a communicable disease as medically or epidemiologically necessary to prevent the spread of the disease, [under conditions he or she may specify;] providing such period of restriction shall not exceed the period of incubation of the disease.

(d) [A] Any person who is responsible for the care, custody, or control of a person who is ill or infected with a communicable disease shall take all measures necessary to prevent transmission of the disease to other persons.

8:57- [1.10] 1.12 Medical examination and specimen submission

(a) The Department or a health officer may order a person who is suspected of being ill or infected with a reportable [or] communicable disease, or who has been exposed to a reportable [or] communicable disease, to submit to a physical examination, X-ray studies, laboratory studies, and such other diagnostic procedures as deemed necessary to determine whether or not such person is communicable to others or is a carrier of disease.

(b) Any person who [is ordered] the Department or health officer orders to submit to an examination and/or to submit specimens under (a) above shall comply with the order.

(c) The Department or health officer shall submit [Specimens] specimens obtained under the authority of this [chapter] subchapter and under the provisions

of this [rule] section [shall be submitted] to a laboratory, which is approved by the Department for the examination of such specimens.

8:57- [1.11] 1.13 Foodhandlers ill or infected with communicable diseases

(a) [A] The Department or a health officer may prohibit a person who is ill or infected with a communicable disease which may be transmitted through food [may, based on the type of organism, job function of the person, and the virulence of the disease, be prohibited by a health officer or the Department] from working [in any occupation that manufactures, processes, stores, prepares, or serves food for public consumption] with food as set forth at N.J.A.C. 8:24-2.2.

(b) [A] The Department or a health officer may prohibit a person who resides in, boards at, lodges in, or visits a household where that person may have come in contact with any person who is ill or infected with a communicable disease which may be transmitted through food [may be prohibited by the health officer or the Department] from working [in any occupation that manufactures, processes, stores, prepares, or serves food for public consumption] with food as set forth at N.J.A.C. 8:24-2.2.

[(b)] (c) [A] The Department or a health officer may require a person who is employed in any establishment where food is manufactured, processed, stored, prepared, or served for public consumption and who is suspected of being ill or infected with a communicable disease which may be transmitted through food [may be required by a health officer or the Department, if a communicable disease

is suspected,] to submit to a physical examination and/or submit specimens of blood, bodily discharges, or other specimens for the purpose of ascertaining whether or not [they are] the person is ill or infected with a communicable disease.

[(c)] (d) [A health officer or the] The Department or a health officer may prohibit the sale or distribution of food which:

1. [Has been prepared by a] A person who is ill or infected with a communicable disease which may be transmitted through food has prepared; or
2. Is considered to be a possible vehicle for spread of disease.

8:57- [1.12] 1.14 Confidentiality

(a) The reports made pursuant to this subchapter shall be used only by the local health department, the Department, and such other agencies as may be designated by the Commissioner to carry out mandated duties, including the duty to control and suppress communicable infectious diseases.

[(b) Medical and epidemiologic information which is gathered in connection with an investigation of a reportable disease or infectious agent and which identifies an individual is confidential and not open to public inspection without that individual's consent, except as may be necessary to carry out duties to protect the public health as determined by a health officer or the Department.]

(b) Information the Department shares with the Secretary of Agriculture involving an overlap agent or toxin that causes or has the potential to cause a public health emergency where the Commissioner suspects or detects conditions that could potentially affect animals, plants or crops under the jurisdiction of the Department of Agriculture pursuant to the provisions of Title 4 of the Revised Statutes shall be held confidential, in accordance with N.J.S.A. 26:13-3d.

(c) The reports submitted to the Department pursuant to N.J.A.C. 8:57-1, except for the reports submitted pursuant to N.J.A.C. 8:57-1.8, contain demographic and medical information related to the Department's investigations and epidemiological studies of communicable diseases and shall not be considered "government records" subject to public access or inspection within the meaning of N.J.S.A. 47:1A-1 et seq. and shall be deemed:

1. "Information relating to medical … history, diagnosis, treatment, or evaluation" within the meaning of Executive Order 26, §4(b)1 (McGreevey, August 13, 2002); and /or

2. "Records concerning morbidity, mortality and reportable diseases of named persons required to be made, maintained or kept by any State or local governmental agency" within the meaning of Executive Order 9, §2(c) (Hughes, September 30, 1963); and/or;

3. Information "for use in the field of forensic pathology or for use in medical or scientific education or research" pursuant to N.J.S.A. 47:1A-1.1.

[(c)](d) Medical or epidemiologic information collected pursuant to this subchapter may be disclosed in statistical or other form, which does not disclose the identity of any person [individual].

8:57-1.15 Enforcement

(a) A physician who fails to report pursuant to the requirements of this subchapter shall be subject to a fine as set forth at N.J.S.A. 26:4-129 and 4-130, or N.J.S.A 26:1A-10.

1. The Department may issue a written notification of this failure and a warning to comply prior to initiating any other enforcement action.

2. The Department may also report the physician's failure to comply with the provisions of this subchapter to the New Jersey Board of Medical Examiners which may initiate disciplinary actions as set forth at N.J.A.C. 13:35-6.24.

(b) An administrator of a health care facility who fails to report pursuant to the requirements of this subchapter shall be subject to a fine as set forth at N.J.S.A. 26:4-129 and 4-130, or N.J.S.A. 26:1A-10.

1. The Department may issue a written notification of this failure and a warning to comply prior to initiating any other enforcement action.

2. The Department may also report the health care facility's failure to comply with the provisions of this subchapter to the New Jersey Department of Health and Senior Services, Division of Health Care Quality and Oversight which may initiate enforcement actions as set forth at N.J.A.C. 8:43E-3.

(c) A clinical laboratory director who fails to report pursuant to the requirements of this subchapter shall be subject to a fine as set forth at N.J.S.A. 26:4-129 and 4-130, or N.J.S.A. 26:1A-10.

1. The Department may issue a written notification of this failure and a warning to comply prior to initiating any other enforcement action.

2. The Department may also report the clinical laboratory director's failure to comply with the provisions of this subchapter to the New Jersey Department of Health and Senior Services, Clinical Laboratory Improvement Service which may initiate enforcement actions as set forth at N.J.S.A. 45:9-42.40, .41, and .43.

(d) A veterinarian, certified animal control officer, or manager of an animal facility who fails to report pursuant to the requirements of this subchapter shall be subject to a fine as set forth at N.J.S.A. 26:4-129 and 4-130, or N.J.S.A. 26:1A-10.

1. The Department may issue a written notification of this failure and a warning to comply prior to initiating any other enforcement action.

2. The Department may also report a veterinarian's failure to comply with the provisions of this subchapter to the New Jersey Board of Veterinary Medical Examiners, which may initiate disciplinary actions as set forth at N.J.S.A. 45:1-21.

(e) A health officer who fails to report pursuant to the requirements of this subchapter shall be subject to a fine as set forth at N.J.S.A. 26:4-129 and 4-130, or N.J.S.A. 26:1A-10.

1. The Department may issue a written notification of this failure and a warning to comply prior to initiating any other enforcement action.

2. The Department may also report the health officer's failure to comply with the provisions of this subchapter to the Department's Public Health Licensing and Examination Board, which may initiate disciplinary actions as set forth at N.J.A.C. 8:7-1.7 and N.J.S.A. 26:1A-43.

(f) A child care center or preschool which fails to report pursuant to the requirements of this subchapter shall be subject to a fine as set forth at N.J.S.A. 26:4-129 and 4-130, or N.J.S.A 26:1A-10.

1. The Department may issue a written notification of this failure and a warning to comply prior to initiating any other enforcement action.

2. The Department may also report the administrator's failure to comply with the provisions of this subchapter to the New Jersey Department of Human Services, Office of Licensing, which may initiate disciplinary actions as set forth at N.J.A.C. 10:122-2.4.

(g) A school or institution of higher education, which fails to report pursuant to the requirements of this subchapter, shall be subject to a fine as set forth at N.J.S.A. 26:4-129 and 4-130, or N.J.S.A 26:1A-10.

1. The Department may issue a written notification of this failure and a warning to comply prior to initiating any other enforcement action.

(h) The administrator of a youth camp, which fails to report pursuant to the requirements of this subchapter, shall be subject to a fine as set forth at N.J.S.A. 26:4-129 and N.J.S.A. 26:4-130.

1. The Department may issue a written notification of this failure and a warning to comply prior to initiating any other enforcement action.

2. The Department may also report the administrator's failure to comply with the provisions of this subchapter to the New Jersey Department of Health and Senior Services, Division of Consumer and Environmental Health which may initiate disciplinary actions as set forth at N.J.A.C. 8:25-14.4 and N.J.A.C. 8:25-14.5.

[8:57-2.1 Applicability; definition of AIDS, and HIV infection, perinatal HIV exposure, and CD4 count

(a) The provisions of this subchapter are applicable to cases of Acquired Immunodeficiency Syndrome (AIDS) and infection with human immunodeficiency virus (HIV). The provisions of N.J.A.C. 8:57-1 shall not apply to any case of AIDS or infection HIV.

(b) Laboratory results indicative of infection with HIV shall mean laboratory results showing the presences of HIV or components of HIV, or laboratory results showing the presence of antibodies to HIV or results from laboratory tests conducted to measure the quantitative presence of HIV RNA (viral load tests), such as quantitative PCR tests. The Commissioner Department of Health and Senior Services shall determine the laboratory tests or test results which indicate infection with HIV for the purpose of these rules. Any such determination shall take effect automatically, without modifying the definition of laboratory results indicative of infection with HIV.

(c) Acquired immunodeficiency syndrome (AIDS) means a condition affecting a person who has a reliably diagnosed disease that meets the criteria for AIDS specified by the Centers for Disease Control of the United States Public Health Services.

(d) A CD4 count means a count of lymphocytes containing the CD4 epitope as determined by the results of lymphocyte phenotyping. An absolute CD4 count means the number of lymphocytes containing the CD4 epitope per

cubic millimeter. A relative CD4 count means the number of such cells expressed as a percentage of total lymphocytes.

(e) A child who is perinatally exposed to HIV is a child born to a woman who is known to be HIV infected at the time of delivery, either through HIV testing prior to or during her pregnancy , or who has been diagnosed as HIV infected through other medical evidence. A child may also be determined to be perinatally exposed through testing at or following birth.]

8:57-2.1 Purpose and scope

(a) The purpose of this subchapter is to establish a framework for the reporting of Human Immunodeficieincy Virus (HIV) infection and Acquired Immunodeficiency Syndrome (AIDS) so that the Department of Health and Senior Services can take action to protect the public health and set standards for maintaining confidentiality in accordance with N.J.S.A. 26:1A-7, N.J.S.A. 26:5C-1 et seq., particularly 26:5C-6 and 26:5C-20.

(b) This subchapter applies to health care providers and institutions that order diagnostic tests for HIV or AIDS, diagnose individuals with HIV or AIDS, or provide treatment for individuals diagnosed with HIV or AIDS, and to clinical laboratories that perform tests indicative of HIV or AIDS and covers reporting standards.

(c) The provisions of N.J.A.C. 8:57-1 shall not apply to any case of AIDS or infection with HIV.

8:57-2.2 Incorporated documents

(a) The Department incorporates by reference, as amended and supplemented, in this subchapter the Centers for Disease Control and Prevention of the United States Public Health Services case definitions of HIV and AIDS available in Volume 41 No. RR-17 of the Morbidity and Mortality Weekly Report (MMWR) published on December 18, 1992 and in Volume 43 No RR-17 of the MMWR published on September 30, 1994 and updates found at www.cdc.gov/mmwr.

(b) The Department incorporates by reference the following forms and instructions in this subchapter.

1. Adult HIV/AIDS Confidential Case Report (DHAS-44) (Appendix A) is a form required for health care providers and responsible parties to report adult cases of HIV and AIDS;

2. HIV/AIDS Laboratory Report (DHAS-43) (Appendix B) is a form required for clinical laboratory directors to report tests defined in this subchapter;

3. Pediatric HIV/AIDS Confidential Case Report (DHAS-45) (Appendix C) is a form required for health care providers and responsible parties to report pediatric cases of HIV, AIDS and pediatric exposures to HIV;

4. The HIV Test Form (OMB No. 0920-0696) Exp. Date: 08/31/2010, as amended and supplemented, produced by the Centers for Disease Control and Prevention (Appendix D) is required for health care providers or responsible

parties using the State Public Health and Environmental Laboratories to perform HIV testing in order to report adult cases of HIV and AIDS, and

i. Instructions for HIV Reporting using the HIV Test Form (Appendix E) are to be used by health care providers or responsible parties testing individuals as part of the New Jersey HIV Counseling and Testing System and using the New Jersey Public Health and Environmental Laboratories.

5. The Instructions for Submission of Positive HIV Diagnostic Specimens (Appendix F) is a set of instructions to be used by health care providers, responsible parties and clinical laboratory directors for sending specimens to the New Jersey Public Health and Environmental Laboratories.

(c) The Department's reporting forms and instructions described in (b)1 through 5 above are available using the following methods:

1. Electronically at the Department's "Forms" webpage http://web.doh.state.nj.us/forms/ or the Division's webpage at www.state.nj.us/health/aids.

2. By contacting the Division of HIV/AIDS Services at (609) 984-5940.

(d) Completed forms shall be addressed to "Surveillance" and mailed to the Division of HIV/AIDS Services at PO Box 363, Trenton, New Jersey 08625-0363 in an envelope marked "Confidential".

1. Health care providers, responsible parties or clinical laboratory directors may contact the Division of HIV and AIDS Services at (609) 984-6940 to request pre-addressed envelopes.

(e) The Department incorporates by reference the Instructions for Electronic Submission of Laboratory Results Indicative of HIV Infection (Appendix G) in this subchapter, which details the requirements for clinical laboratory directors to report tests defined in this subchapter and is available on the Division's webpage at www.state.nj.us/health/aids.

8:57-2.3 Definitions

The following words and terms, when used in this subchapter shall have the following meanings unless the context clearly indicates otherwise.

"Acquired Immunodeficiency Syndrome" or "AIDS" means a condition affecting an individual who has a reliably diagnosed disease that meets the criteria for AIDS specified by the Centers for Disease Control and Prevention of the United States Public Health Services in Volume 41 No. RR-17 of the Morbidity and Mortality Weekly Review (MMWR) published on December 18, 1992 and in Volume 43 No. RR-17 of the MMWR published on September 30, 1994 and updated in Volume 48 No. RR-13 of the MMWR published on December 10, 1999.

"Audit" means the review of medical records to determine the type and dates of services related to HIV infection provided by a health care provider, responsible party, or institution, and to verify compliance with this subchapter.

"CD4 count" means a count of lymphocytes containing the CD4 epitope as determined by the results of lymphocyte phenotyping.

1. An absolute CD4 count means the number of lymphocytes containing the CD4 epitope per cubic millimeter.

2. A relative CD4 count means the number of such cells expressed as a percentage of total lymphocytes.

"Division" means the Division of HIV/AIDS Services located in the Department.

"Epidemiologic investigations" means the review of medical records to determine disease progression, co-morbidities of other diseases with HIV or AIDS, treatments prescribed, laboratory test results, and other characteristics of individuals diagnosed with HIV infection or AIDS.

"Human Immunodeficiency Virus" or "HIV" means the virus that causes AIDS and that meets the case definition of HIV specified by the Centers for Disease Control and Prevention of the United States Public Health Services in Volume 41 No. RR-17 of the Morbidity and Mortality Weekly Review (MMWR) published on December 18, 1992 and in Volume 43 No. RR-17 of the MMWR published on September 30, 1994 and updated in Volume 48 No. RR-13 of the MMWR published on December 10, 1999.

"Institution" means a hospital, sanitarium, nursing home, correctional facility, clinic, blood bank, insurance company or facility for HIV counseling and testing.

"Laboratory HIV results" means clinical laboratory results showing the presence of HIV or components of HIV, or laboratory results showing the presence of antibodies to HIV, or results from laboratory tests conducted to measure the quantitative presence of HIV ribonucleic acid (RNA) (viral load

tests), such as quantitative polymerase chain reaction (PCR) tests, or tests used only for HIV infected individuals.

"Perinatally exposed" means that a child is born to a woman who is known to be HIV infected at the time of delivery, either through HIV testing prior to or during her pregnancy, or diagnosed by a health care provider.

"Responsible party" means the individual having control or supervision over any institution such as a chief administrator.

[8:57-2.2] 8:57-2.4 Reporting HIV Infection for health care providers and responsible parties

(a) [Every physician attending a person] A health care provider or responsible party for an institution providing services to an individual found to be infected with HIV, or ordering a test resulting in the diagnosis of HIV, shall, within 24 hours of receipt of a laboratory report indicating such a condition, or within 24 hours of making a diagnosis of HIV infection [or AIDS], report in writing [such condition directly] to the Department [of Health and Senior Services on forms supplied by the Department of Health and Senior Services. The report shall include the name and address of the reporting physician, the name, address, gender, race and birth date of the person found to be infected with HIV, the date the specimen tested for HIV was obtained, and such other information as may be required by the Department of Health and Senior Services. A physician shall not report a person infected with HIV if the physician is aware that the person having

control or supervision of an institution named in (b) below is reporting that person as being infected with HIV, or if the physician is aware that the person has previously been reported to the Department of Health and Senior Services as being infected with HIV. The Department of Health and Senior Services may also collect additional information on persons previously reported, for either audit or epidemiological purposes.] using the Adult HIV/AIDS Confidential Case Report Form, available at Appendix A.

(b) A health care provider or responsible party testing individuals as part of the New Jersey HIV Counseling and Testing System and using the New Jersey Public Health and Environmental Laboratories shall, within 24 hours of receipt of a laboratory report indicating such a condition, report in writing such condition directly to the Department using the HIV Test Form, available at Appendix D.

i. The health care provider or responsible party shall use the Instructions for HIV Reporting using the HIV Test Form, available at Appendix E.

[(b) The person having control or supervision over any institution such as a hospital, sanitarium, nursing home, penal institution, clinic, blood bank, insurance company or facility for HIV counseling and testing in which any person is determined to be infected with HIV shall, within 24 hours of receipt of a laboratory report indicating such a condition, report in writing such condition directly to the Department of Health and Senior Services on forms supplied by the Department of Health and Senior Services. The report shall state the name, address, gender, race, and birth date of the person found to be infected with HIV,

the date the specimen tested for HIV was obtained, the name of the attending physician, the name and address of the institution, and such other information as may be required by the Department of Health and Senior Services. The person having control or supervision of the institution shall not report a person infected with HIV if it is known that a physician is reporting the person or that the person has previously been reported to the Department of Health and Senior Services as being infected with HIV.]

(c) [The person having control or supervision of the institution] A health care provider or responsible party, may delegate this reporting activity to a member of the staff, but this delegation does not relieve the [controlling or supervising person] health care provider or responsible party of the ultimate reporting responsibility. [The Department of Health and Senior Services may also collect additional information on persons previously reported, for either audit or epidemiological purposes]

(d) A health care provider or responsible party who provides medical services to an individual found to be infected with HIV, or orders tests resulting in the diagnosis of HIV, shall make the names of the individuals infected with HIV along with their medical records available to the Department for audit or epidemiologic investigation.

[8:57-2.2(c)] 8:57-2.5 Reporting HIV infection for clinical laboratories

[(c)] (a) [Every] A clinical laboratory director shall, within five working days of completion of a quantitative [PCR (viral load) test], Polymerase Chain

Reaction (PCR) also known as a viral load test regardless of test result, or any other laboratory test which has results indicative of infection with HIV, report such results to the Department [of Health and Senior Services. The report shall include the name and address of the clinical laboratory, the name and address of the submitter of the laboratory specimen, the date of the test, and the name, address, gender, and date of birth of the person from whom the laboratory specimen was obtained, or a unique code if a code is the only information identifying the person from whom the laboratory specimen was obtained, and other epidemiological information as may be required by the Department of Health and Senior Services on a general or a case-by-case basis.] using one of the following two methods:

1. An electronic file in accordance with the Instructions for Electronic Submission of Laboratory Results Indicative of HIV Infection, available at Appendix G; or

2. The HIV/AIDS Laboratory Report Form (DHAS-43), available at Appendix B.

[Only specimens sent to the laboratory from physicians' offices in New Jersey or from institutions in New Jersey should be reported.]

(b) The clinical laboratory director shall only report specimens sent to the clinical laboratory from a healthcare provider or institution located in New Jersey, or obtained from residents of New Jersey.

[8:57-2.3] 8:57-2.6 Reporting children perinatally exposed to HIV

(a) [Every physician attending] A health care provider or responsible party for an institution providing care to a child known to be perinatally exposed to HIV, or ordering a test resulting in the diagnosis of perinatally exposed HIV, shall, within 24 hours of receipt of a laboratory report indicating such a condition report in writing such condition directly to the Department [of Health and Senior Services on forms supplied by the Department of Health and Senior Services. The report shall include the information as in N.J.A.C. 8:57-2.2(a), and such other information as may be required by the Department of Health and Senior Services.] using the Pediatric HIV/AIDS Case Report Form (DHAS-45), available at Appendix C. [A physician shall not report the child perinatally exposed to HIV if the physician is aware that the person having control or supervision of an institution named in (b) below is reporting that child as being infected with HIV, or if the physician is aware that the child has previously been reported to the Department of Health and Senior Services as being perinatally exposed to HIV. The Department of Health and Senior Services may also collect additional information on children previously reported, for either audit or epidemiological purposes.

(b) The person having control or supervision over any institution such as a hospital, sanitarium, nursing home, penal institution, clinic, blood bank, insurance company or facility for HIV counseling and testing in which a child is determined to be perinatally exposed to HIV shall, within 24 hours of receipt of a laboratory report or other medical evidence indicating such a condition, report in writing

such condition directly to the Department of Health and Senior Services on forms supplied by the Department of Health and Senior Services. The report shall include the information as in N.J.A.C. 8:57-2.2(a), and such other information as may be required by the Department of Health and Senior Services. The person having control or supervision of the institution shall not report a child perinatally exposed to HIV if it is known that a physician is reporting the child or that the child has previously been reported to the Department of Health and Senior Services as being perinatally exposed to HIV.]

(b) The [person having control or supervision] health care provider or responsible party of the institution may delegate this reporting activity to a member of the staff, but this delegation does not relieve the [controlling or supervising person] health care provider or responsible party of the ultimate reporting responsibility. [The Department of Health and Senior Services may also collect additional information on children previously reported, for either audit or epidemiological purposes.]

(c) A health care provider attending a child who was exposed perinatally to HIV or the responsible party at an institution in which any child is determined to have been perinatally exposed to HIV shall make the medical records of the mother and child available to the Department for audit or epidemiologic purposes.

[8:57-2.4] 8:57- 2.7 Reporting AIDS for Health Care Providers and Responsible Parties

(a) [Every physician attending any person ill with AIDS] A health care provider or responsible party for an institution providing services to an individual determined to be diagnosed with AIDS shall, within 24 hours of the time AIDS is diagnosed, report in writing such condition directly to the Department [of Health and Senior Services on forms supplied by the Department of Health and Senior Services. The report shall include the name and address of the reporting physician, the name, address, gender, race, and birth date of the person ill with AIDS, the date of onset of the illness meeting the criteria for the diagnosis of AIDS, and such other information as may be required by the Department of Health and Senior Services. [Such report should be made whether or not the patient previously had been reported as having HIV infection. Such report should be made whether or not the patient previously had been reported as having HIV infection.] using the Adult HIV/AIDS Confidential Case Report Form (DHAS-44), available at Appendix A.

(b) The health care provider or responsible party may delegate this reporting activity to a member of the staff, but this delegation does not relieve the health care provider or responsible party of the ultimate reporting responsibility.

(c) A health care provider or responsible party shall complete the required report established at (a) above regardless of whether the patient previously had been reported as having HIV infection.

(d) The report of AIDS will be deemed to also be a report of HIV infection. [The Department of Health and Senior Services may also collect

additional information on persons previously reported, for either audit or epidemiological purposes.]

[(b) The person having control or supervision over any institution, such as a hospital, sanitarium, nursing home, penal institution, or clinic, in which a person is ill with AIDS shall within 24 hours of the time AIDS is diagnosed, report such condition in writing directly to the Department of Health and Senior Services on forms provided by the Department of Health and Senior Services. The report shall state the name, address, gender, race and birth date of the person ill with AIDS, the date of onset of the illness meeting the criteria for the diagnosis of AlDS, the name of the attending physician, the name and address of the institution, and such other information as may be required by the Department of Health and Senior Services. Such report should be made whether or not the patient previously had been reported as having HIV infection. The report of AIDS will be deemed to also be a report of HIV infection. The person having control or supervision of the institution may delegate this reporting responsibility to a member of the staff, but this delegation does not relieve the controlling or supervising person of the ultimate reporting responsibility. The Department of Health and Senior Services may also collect additional information on persons previously reported, for either audit or epidemiological purposes.]

(e) A health care provider attending an individual found to be diagnosed with AIDS or the health care provider or responsible party at any institution shall make the

names of the individuals diagnosed with AIDS along with their medical records available to the Department for audit or epidemiologic purposes.

[8:57-2.4(c)] 8:57-2.8 Reporting AIDS for Clinical Laboratories

[(c)] (a) [Every] A clinical laboratory director shall, within five working days of completion of a CD4 count which has absolute or relative results below a level specified by the Centers for Disease Control and Prevention as criteria for defining AIDS, report [in writing or electronically such results to the Department of Health and Senior Services. The report shall include the name and address of the clinical laboratory, the name and address of the submitter of the laboratory specimen, the date of the test, and the name, address, gender, and date of birth of the person from whom the laboratory specimen was obtained, or a unique code if a code is the only information identifying the person from whom the laboratory specimen was obtained, and other epidemiological information as may be required by the Department of Health and Senior Services on a general or a case-by-case basis] such results to the Department using one of the following methods:

1. An electronic file in accordance with the Instructions for Electronic Submission of Laboratory Results indicative of HIV infection, available in Appendix G; or

2. The HIV/AIDS Laboratory Report Form (DHAS-43), available in Appendix B.

[Only specimens sent to the laboratory from physicians' offices in New Jersey or from institutions in New Jersey should be reported.]

(b) The clinical laboratory director shall only report specimens sent to the clinical laboratory from a health care provider or institution located in New Jersey, or obtained from residents of New Jersey.

[8:57-2.5] 8:57-2.9 Testing procedures

(a) No [physician or institution] health care provider or responsible party may direct a person to be tested for HIV, a component of HIV, or antibodies to HIV, unless the name and address of the person whose specimen is being tested is known and recorded by the health care provider or administrator, except that the Commissioner, [Department of Health and Senior Services] may designate facilities which are permitted to test for antibodies to HIV without obtaining the name and address of the person being tested. [The name and address of a person requesting testing without giving his or her name and address at such a designated facility are not required to be reported to the Department of Health and Senior Services.]

1. The Department does not require a health care provider or responsible party to report the name or address of any individual that requests testing at a facility designated by the Commissioner to test for HIV anonymously.

[8:57-2.6 Exceptions to Communicable Disease Classification of AIDS and HIV

(a) AIDS or HIV infection shall not be considered a communicable disease for purposes of admission to, attendance in, or transportation in any of the following:

1. Nursing homes and other health care facilities;

2. Rooming and boarding homes, and shelters for the homeless;

3. Ambulances and other public conveyances; and

4. Educational facilities]

8:57-2.10 Specimen Submissions

(a) A health care provider, responsible party or clinical laboratory director shall, within 24 hours of completion of a confirmatory diagnostic test indicative of HIV infection, send the residual specimen of such test to the State's Public Health and Environmental Laboratories (PHEL) except as noted in (b) below.

1. The specimen must contain identifying information so that the Department can link the specimen to the identifying information contained in the reports required at N.J.A.C. 8:57-2.5 and 2.8.

2. The specimen shall be sent in accordance with the Instructions for Submission of Positive HIV Diagnostic Specimens, available at Appendix F.

(b) A health care provider or responsible party shall not send a specimen to the PHEL if they obtained the specimen from an individual without identifying information at a facility designated by the Commissioner to test for HIV anonymously.

[8:57-2.7] 8:57-2.11 Access to Information

(a) The forms submitted to the Department pursuant to N.J.A.C. 8:57-2 contain demographic and medical information related to the Department's investigations and epidemiologic studies of HIV and AIDS and shall not be considered "government records" subject to public access or inspection within the meaning of N.J.S.A. 47:1A-1 et seq. and shall be deemed:

1. "Information relating to medical . . . history, diagnosis, treatment, or evaluation" within the meaning of Executive Order 26, §4(b)1 (McGreevey, August 13, 2002); and/or

2. "Records concerning morbidity, mortality and reportable diseases of named individuals required to be made, maintained or kept by any State or local governmental agency" within the meaning of Executive Order 9, §2(c) (Hughes, September 30, 1963); and/or

3. Information "for use in the field of forensic pathology or for use in medical or scientific education or research" pursuant to N.J.S.A. 47:1A-1.1.

(b) As provided by N.J.S.A. 26:4-2 and 26:5C-5 through 14, the information reported to the Department shall not be subject to public inspection, but shall be subject to access only by the Department [of Health and Senior Services] for public health purposes.

(c) The Department may release data in summary format without identifying information in the form of reports and epidemiologic profiles.

[8:57-2.8] 8:57-2.12 Failure to comply with reporting requirements

(a) [Physicians] The Department shall provide written notification to health care providers that [failing] fail to fulfill the reporting requirements of this subchapter [may receive written notification of this failure].

1. [Physicians] Health care providers failing to meet these reporting requirements, despite warning, shall be subject to fines, as allowed by N.J.S.A. 26:4-129 and 4-1.30.

2. [In addition, those whose failure to report is determined by the Department of Health and Senior Services to have significantly hindered public health control measures] Health care providers shall be subject to other actions, including notification of the Board of Medical Examiners of the State Department of Law and Public Safety, and appropriate hospital medical directors or administrators.

(b) [The person having control or supervision over any] The Department shall provide written notification to the responsible party for an institution, who fails to fulfill the [aforementioned] reporting obligations of this subchapter, [may receive written notification of this failure].

1. [Superintendents] A responsible party failing to meet these reporting requirements, despite warning, shall be subject to a fine, as allowed by N.J.S.A. 26:4-129 and 4-1.30.

2. [In addition, those whose failure to report is determined by the Department of Health and Senior Services to have significantly hindered public

health control measures, the] The responsible party shall be subject to other actions, including notification of the Department's [of Health and Senior Services, Division of Health Planning and Regulation,] Health Facilities Evaluation and Licensing Division, other appropriate licensing review organizations, and other appropriate agencies.

(c) The Department shall provide written notification to clinical laboratory [supervisors] directors that [failing] fail to fulfill the aforementioned reporting obligations [may receive written notification of this failure].

1. [Supervisors] Clinical laboratory directors failing to meet these requirements, despite warning, shall be subject to fines as allowed by N.J.S.A. 26:4-129 and 4-1.30.

2. [In addition, those whose failure to report is determined by the Department of Health and Senior Services to have significantly hindered public health control measures, the] The clinical laboratory director shall be subject to other actions, including notification of the [State] Department's Clinical Laboratory Improvement [Services] Service.

Recodify N.J.A.C. 8:57-3 as N.J.A.C. 8:58

N.J.A.C. 8:57-3 (Reserved.)

8:57-4.6 Documents accepted as evidence of immunization

(a)-(b) (No change.)

(c) Laboratory evidence of protective immunity, as enumerated by the Advisory Committee on Immunization Practices (ACIP) of the United States Public Health Service, shall be accepted as evidence of immunization if a parent or guardian cannot produce a documented history of immunization.

8:57-4.12 Measles virus vaccine

(a)-(d) (No change.)

[(e) Children who present documented laboratory evidence of measles immunity shall not be required to receive the first or second dose of measles vaccine.]

Recodify existing (f) as (e) (No change in text.)

8:57-4.13 Rubella vaccine

(a)-(b) (No change.)

[(c) Rubella virus vaccine shall not be required of children who present documented laboratory evidence of rubella immunity]

8:57-4.14 Mumps vaccine

(a)-(c) (No change.)

[(d) Children who present documented laboratory evidence of mumps immunity shall not be required to receive mumps vaccine.]

8:57-4.18 Pneumococcal conjugate vaccine

(a) Every child from two months through 11 months of age enrolling in or attending any child-care center [or preschool facility] on or after September 1, 2008 shall have received a minimum of two age-appropriate doses of pneumococcal conjugate vaccine (PCV), or fewer as medically appropriate for the child's age according to the ACIP recommendations, incorporated herein by reference, as amended and supplemented.

1. (No change.)

(b) Every child 12 months through 59 months of age enrolling in or attending a child care center or preschool facility on or after September 1, 2008 shall have received at least one dose of PCV on or after their first birthday.

SUBCHAPTER 5. [CONFINEMENT OF PERSONS WITH TUBERCULOSIS]

MANAGEMENT OF TUBERCULOSIS

8:57-5.1 Purpose and scope

(a) The purpose of [these rules] this subchapter is to control the spread of tuberculosis (TB) [, particularly new forms of multiple drug resistant TB (MDR-TB),] by maximizing the use of currently available and highly effective treatments.

(b) [These rules apply] This subchapter applies to persons who have [active] suspected or confirmed TB disease [or who are suspected of having active TB disease] as diagnosed by a health care provider [or local health officer, as well

as those persons identified either as contacts to a person(s) with active or suspected active TB disease or those with TB infection when active TB has not been ruled out] , especially those with suspected or confirmed infectious or potentially infectious TB disease who pose an immediate or imminent risk to the public health. 1. This includes persons identified by public health professionals as contacts to persons with suspected or confirmed infectious or potentially infectious TB disease, and Class B1 or B2 referrals from the Centers for Disease Control and Prevention (CDC) who are residing in New Jersey.

(c) Local health officers, public health nurse case managers, health care providers and administrators of hospitals and correctional facilities are primarily responsible for implementation of [these rules] this subchapter. [Physicians and other providers of health care services, including, but not limited to, managed care organizations, hospital administrators and emergency medical technicians, also have responsibilities under these rules.]

(d) Local health officers in areas where the person with suspected or confirmed, infectious or potentially infectious TB disease resides, frequents or receives care may take any action authorized under [these rules] this subchapter if [the local health officer] he or she determines that [they are] it is necessary [for] to protect the health of the person or the public. [Such local health officers shall notify the local health officer with primary responsibility, within 72 hours, of any actions taken under these rules.]

(e) The guiding [principles] goals underlying [the implementation of these rules] this subchapter are:

1. To protect the public from the spread of [active] TB disease and/or latent TB infection; and

2. To diagnose and treat persons with [active TB or suspected TB] suspected or confirmed TB disease and those with latent TB infection at high risk for progression to TB disease in the least restrictive environment and manner.

8:57-5.2 Incorporated documents

(a) To further the purposes of this subchapter, the Department incorporates by reference, as amended and supplemented, Morbidity and Mortality Weekly Report (MMWR), Treatment of Tuberculosis, published by the Centers for Disease Control and Prevention on June 20, 2003, volume 52, number RR-11, (hereinafter MMWR, Treatment of Tuberculosis).

1. The MMWR, Treatment of Tuberculosis is available by written request to the Communicable Disease Service, Public Health Services Branch, New Jersey Department of Health and Senior Services, PO Box 369, Trenton, NJ, 08625-0369, or online at the Centers for Disease Control and Prevention's web page at http://www.cdc.gov/mmwr/PDF/rr/rr5211.pdf.

(b) The Department incorporates by reference the following forms in this subchapter:

1. TB-70: Tuberculosis Case, Suspect and Status Report (Appendix A) is the form for reporting suspected or confirmed TB disease and updating the status of these patients.

2. TB-41: Record of Contact Interview (Appendix B) is the form for reporting the identification, results of medical evaluation and final disposition of contacts.

(c) All of the forms in (b) above are available by written request to the Communicable Disease Service, Public Health Services Branch, New Jersey Department of Health and Senior Services, PO Box 369, Trenton, NJ 08625-0369.

1. The TB-41form is also available online through the Department's "Forms" web page at http://web.doh.state.nj.us/forms/.

8:57-[5.2] 5.3 Definitions

The following words and terms, as used in this subchapter, shall have the following meanings, unless the context clearly indicates otherwise:

"Acid-fast bacilli (AFB)" means organisms that remain stained after being washed in acid solution, may be detected using a microscope, and are then reported as a positive AFB on smear.

1. TB should be considered a possibility when AFB are present on a stained smear, [which] and indicates the likelihood of infectiousness [in a TB patient] if from a pulmonary source such as, but not limited to, sputum,

bronchioalveolar lavage, gastric aspirate, lung tissue, as well as other tissue of the respiratory tract such as the larynx or epiglottis.

["Active TB" means that:

1. A person has a positive smear for acid-fast bacilli (AFB) or culture identified as Mycobacterium tuberculosis (M.tb) or M.tb complex taken from a pulmonary source such as sputum, bronchioalveolar lavage, gastric aspirate, lung tissue, etc. as well as other tissue of the respiratory tract such as the larynx or epiglottis, and the person has not completed a prescribed course of medication for tuberculosis according to the latest American Thoracic Society (ATS) and Centers For Disease Control and Prevention (CDC) guidelines; or

2. A specimen collected from a non-pulmonary site indicating the likelihood (acid-fast bacilli or granulomas present) or confirmation of tuberculosis disease by culture (M.tb or M.tb complex), and there is clinical evidence or clinical suspicion of pulmonary tuberculosis disease, and the person has not completed an appropriate prescribed course of medication for tuberculosis; or

3. In those cases where smears and/or cultures are unobtainable or are negative, the radiographic and clinical findings as well as epidemiological evidence are sufficient to highly suspect a medical diagnosis of pulmonary tuberculosis for which treatment is recommended.]

"Administrator" means any person having control or supervision over a hospital or correctional facility.

[“Appointment keeping rate” means the number of kept appointments divided by the number of scheduled appointments.

“Clinically suspected active TB” means a condition in which the person presents a substantial likelihood, as determined by a health care provider, of having active tuberculosis that is infectious, based upon epidemiologic evidence, clinical evidence, x-ray readings, or laboratory test results.]

“Class B1 or B2 referrals” means referrals from the CDC’s Division of Global Migration and Quarantine which informs the Department of persons who are refugees, parolees, asylees, or recent legal immigrants to the United States, and who were screened overseas and classified as either B1 meaning TB, clinically active, not infectious or B2 meaning TB, not clinically active, not infectious.

1. These classifications are made within 12 months of immigration and these referrals require evaluation of their TB status within 30 days of arrival to prevent potential transmission.

[“Close contact” means a person, as identified by a health care provider or his or her designee or by an agent of the State or local health department, who shares common living, recreational, working, transportation or other areas with a person with active tuberculosis such that the frequency of exposure and/or proximity of those contacts to the case may cause transmission of tuberculosis.

“Commissioner” means the Commissioner of the Department of Health and Senior Services or his or her designee.

"Compliance" means that a person takes 80 percent or more of his or her prescribed TB medication. The term "compliance" is equivalent to the term "adherence," a term often used by the Centers for Disease Control and Prevention.]

"Contact" means a person identified by the public health department who has had exposure to a patient with suspected or confirmed infectious or potentially infectious TB sufficient in both duration and proximity to make him or her at increased risk for recent transmission of latent TB infection.

["Designated commitment facility or unit" means a health care facility selected by the Commissioner, Department of Health and Senior Services to provide one or more of the following when involuntary commitment is required under these rules: space for involuntary commitment; space and clinical program for involuntary examination and treatment; and/or space and clinical program for commitment and facilities for hearings under this subchapter.]

"Directly observed therapy (DOT)" means [a methodology for ensuring compliance with medication directions in which a health care provider or trained designee witnesses the person ingesting his or her prescribed medications] the observation, by a person who is trained in the performance of these duties, of the ingestion of anti-TB medication by a patient.

1. DOT is the only method available to reliably determine a patient's adherence to a prescribed treatment regimen.

"Extensively drug resistant tuberculosis (XDR-TB)" means a form of TB disease that is resistant to at least isoniazid, rifampin, any fluoroquinolone, and either amikacin, kanamycin or capreomycin.

"Field services" means the provision of directly observed therapy (DOT) as ordered by a health care provider.

1. Field services may also include other services the field services provider is trained and equipped to perform (such as, but not limited to, patient interviews, transportation, delinquent investigations).

"Health care provider" means a person who is directly involved in the clinical diagnosis of and the prescribing of medication for individuals with suspected or confirmed TB disease or latent TB infection.

1. [These individuals would] Health care providers include physicians, [nurses, nurse practitioners, clinical nurse specialists], advanced practice nurses, certified nurse midwives, and/or [physicians] physician assistants.

"Health officer order" means an order issued by a [local] health officer to a [person who has ignored a warning notice regarding the need to comply with appropriate medical action as requested by a health care provider] patient with suspected or confirmed infectious or potentially infectious TB disease, a contact, or a class B1 or B2 referral at a specified time as described in N.J.A.C. 8:57-5.10 through 5.12.

"Hospital" shall have the meaning set forth in the Department's Hospital Licensing Standards for general hospital and special hospital at N.J.A.C. 8:43G-1.3(b), which treat patients with TB disease.

"Immediate or imminent public health risk" means a patient with suspected or confirmed infectious or potentially infectious TB disease and who does any of the following:

1. Threatens to leave an acute care facility against medical advice;

2. Leaves an acute care facility against medical advice;

3. States he or she will not adhere to infection control measures;

4. Does not adhere to infection control measures;

5. Refuses to take anti-tuberculosis medication as prescribed; or

6. Threatens to travel on a public conveyance.

"Index case" means the patient with suspected or confirmed infectious or potentially infectious TB disease or child less than five years of age whose diagnosis results in a source case investigation.

"Infection control measures" means restrictions imposed by a health care provider, nurse case manager, or health officer to protect the public from transmission of tuberculosis from a patient with suspected or confirmed infectious or potentially infectious TB disease.

1. The measures applicable to each patient will vary based upon the circumstances of the individual.

[“Infectious tuberculosis” means the stage of tuberculosis, as determined by laboratory, radiologic, epidemiologic or clinical findings, where mycobacterial organisms are capable of being expelled into the air by a person.]

“Interferon gamma release assay” means QuantiFERON-Gold or T-spot.TB assay.

“Latent TB infection” means the presence of Mycobacterium tuberculosis [germs] bacteria in the body as [detected by] evidenced by a significant reaction to a Mantoux tuberculin skin test [but without TB disease] or positive interferon gamma release assay.

1. A person with latent TB infection does not have an illness nor is he or she infectious.

“Least restrictive [alternative] environment or manner” means the intervention that limits the [person’s] patient’s activities the least [balanced against the risk to the public and individual persons based on the likelihood that transmission of TB infection could occur] while providing protection for the public against the likelihood of TB transmission.

[“Local health officer” means a holder of an active license as a health officer as issued by the New Jersey Department of Health and Senior Services in accordance with applicable laws, or his or her duly authorized representative. Unless otherwise indicated, the local health officer who has primary responsibility under these rules is the local health officer of the jurisdiction in which the patient resides.

"Loss of contact" means that two documented attempts on different days and at different times, by a health care provider or his or her designee or by an agent of the Department of Health and Senior Services or a local health officer or his or her designee, to conduct a face to face meeting with a person failed because the individual was not at his or her last known residence or designated location. In the case of persons with no current address, last known residence refers to a discrete geographic area in a community in which the person was last seen with some degree of regularity.

"Manager, TB Program" means the Manager of the TB Program in the Division of Epidemiology, Environmental, and Occupational Health, New Jersey Department of Health and Senior Services, or his or her designee.

"Medical director" means the physician with clinical responsibility for a designated commitment facility/unit.]

"Multiple drug resistant tuberculosis (MDR-TB)" means a form of TB disease that is resistant to at least [Izoniazid] isoniazid and [Rifampin] rifampin [as included in the Joint Statement of the American Thoracic Society and the Centers for Disease Control and Prevention: "Treatment of Tuberculosis and Tuberculosis Infection in Adults and Children," March 1993, as amended and supplemented].

"Nucleic acid amplification test" means polymerase chain reaction (PCR) or *Mycobacterium tuberculosis* direct (MDT) test.

"Public Health Nurse Case Manager" means the nurse providing public health nurse case management services which include, but are not limited to:

1. Patient education regarding the transmission of TB, how to prevent it, and the importance of keeping appointments for clinical assessments and completing treatment;

2. Facilitating the continuity of care for a patient with suspected or confirmed TB until treatment completion by scheduling diagnostic evaluations in a timely manner, monitoring adherence with prescribed therapy, and intervening as appropriate and necessary to address non-adherence;

3. Assessing adherence with community infection control precautions and intervening as appropriate and necessary to address non-adherence;

4. Coordination of TB care with the care of co-existing medical conditions among multiple medical providers;

5. Assessing the quality of care provided by both public and private health care providers with intervention as necessary;

6. Identification of psycho-social barriers to adherence and treatment completion, including, but not limited to: housing, food, transportation, communication, child care, parenting, incarceration, substance abuse and mental illness and intervention as necessary to promote the continuity of treatment;

7. Coordination of contact or source case investigation and care, including, identification, evaluation and appropriate treatment of all identified contacts;

8. Coordination of investigations for all Class B1 and B2 referrals including location, evaluation, and initiation of appropriate treatment;

9. Coordination of all field services, including provision of DOT as prescribed by a health care provider; and

10. Building and maintaining effective working relationships with infection control professionals at hospitals and private health care providers that identify and report tuberculosis in the designated coverage area.

"Public health warning notice" means a notice issued by a public health nurse case manager to a patient with suspected or confirmed infectious or potentially infectious TB disease, a contact, or class B1 or B2 referral as specified in N.J.A.C. 8:57-5.10.

["Restraining order" means an order issued by a local health officer or Superior Court to an individual hospitalized with active or clinically suspected active tuberculosis to prevent the individual from leaving the hospital against medical advise.]

"Risk for flight" means any of the following circumstances pertaining to a patient with suspected or confirmed infectious or potentially infectious TB disease posing an immediate or imminent public health risk:

1. Threatens to leave acute care facility against medical advice;

2. Has left acute care facility against medical advice in the past;

3. Threatens not to appear in court;

4. Has failed to appear in court in the past;

5. Is homeless or residency is unstable;

6. Has been lost to medical supervision in the past; or

7. Threatens to travel on a public conveyance.

[“Social resources” means services which allow the person to successfully complete the prescribed course of treatment, including, but not limited to, food, housing, transportation, and communication.]

“Source case investigation” means the process of identification and evaluation of associates of a patient aged 10 years or less with suspected or confirmed TB disease for the purpose of finding the source of the child’s disease and interrupting additional transmission.

“Suspected or confirmed infectious or potentially infectious TB disease” means one or more of the following:

1. A patient with a smear positive for AFB and/or nucleic acid amplification test positive for *M.tb* and/or a culture positive for *M.tb* or *M.tb* complex;

i. This applies only to specimens from sputum, brochioalveolar lavage, gastric aspirate, lung tissue or other tissue of the respiratory tract such as the larynx or epiglottis;

2. A patient with a chest radiograph, computed tomography scan, or clinical findings indicative of pulmonary tuberculosis sufficient to prescribe treatment with anti-tuberculosis medications;

3. A patient whose chest radiograph or respiratory symptoms improve while taking anti-tuberculosis medication; or

4. A patient with respiratory symptoms indicative of pulmonary tuberculosis until a diagnostic evaluation is completed to rule out TB as a cause of these symptoms.

"Suspected or confirmed TB disease" means one or more of the following:

1. A patient meeting the definition of suspected or confirmed infectious or potentially infectious TB disease;

2. A patient with a smear positive for AFB and/or nucleic acid amplification test positive for *M. tuberculosis* and/or a culture positive for *M. tuberculosis* or *M. tuberculosis* complex from a location outside the respiratory tract;

3. A patient with extra-pulmonary clinical findings indicative of tuberculosis sufficient to prescribe treatment with anti-tuberculosis medications;

4. A patient whose extra-pulmonary symptoms improve on anti-tuberculosis medications; or

5. A patient with symptoms indicative of extra-pulmonary tuberculosis until a diagnostic evaluation is completed to rule-out TB as the cause of these symptoms.

["TB control agency" means a facility or organization that has the designated responsibility for TB control activities, usually covering a set

geographic area. This may be a county or local health department, state recognized chest clinic, or other authorized agency.]

"Vulnerable population" means persons who are vulnerable to rapid progression to TB disease once infected including, but not limited to, persons with the following conditions or on the following treatments: HIV infection, corticosteroid therapy, tumor necrosis factor (TNF) alpha blocker therapy, cancer chemotherapy, end-stage renal disease, cancer of the head or neck, or children under the age of five years.

["Warning notice" means a notice written by a health care provider or health officer informing a person, after several missed appointments or failure of the patient to comply with an acceptable treatment plan, of the public health requirements in the State of New Jersey as they relate to the evaluation and/or treatment of an active or clinically suspected active TB case, close contact, or individual with latent TB infection.]

8:57-5.4 Reporting requirements

(a) Health care providers and administrators providing care for any person with a diagnosis of suspected or confirmed TB disease at any site shall report to the Department's TB program or designee the following circumstances utilizing the TB-70 form, available at Appendix A:

1. A person with suspected or confirmed TB disease within 24 hours of diagnosis;

i. A health care provider shall report a patient as a TB suspect within 24 hours of initiation of treatment.

2. Updated monthly information on patients with suspected or confirmed TB disease under their care whenever any of the following occurs: change in clinical status, change in the treatment regimen, treatment ceases for any reason, new laboratory findings, new radiographic findings, change in medical supervision or change in patient locating or contact information;

i. The health care provider or administrator shall submit a TB-70 form if any of these events occur, by the tenth day of the following month; and

3. Absent any of the occurrences in (a)2 above, health care providers and administrators shall report updated information on patients with suspected or confirmed TB disease under their care at least every three months after the confirmation of TB disease while treatment is on-going.

(b) The public health nurse case manager shall submit a TB-70 form to the Department's TB Program for patients in accordance with (a)1 through 3 above for patients with suspected or confirmed TB residing in the local health jurisdictions for which he or she has responsibility, when a public health clinic is medically managing these patients.

(c) Health care providers and administrators may report the information required by the TB-70 form to the Department's TB Program Surveillance Unit by telephone (609) 588-7522, or by mail to: New Jersey Department of Health and Senior Services, TB Program, PO Box 369, Trenton, NJ 08625-0369.

1. Health care providers and administrators may also submit the TB-70 form to an appropriate designee of the Department.

i. Health care providers and administrators may call the Department's TB Program to determine the appropriate local designee.

2. Public health nurse case managers shall submit the TB-70 form to the TB Program through the mailing address provided above.

(d) The public health nurse case manager for the jurisdiction in which an index case resides shall report to the Department utilizing the TB-41 form, available at Appendix B, the identification, evaluation results and final disposition of contacts of the index case with suspected or confirmed TB disease with the following characteristics:

1. Nucleic acid amplification test positive for *M.tb* from a sputum specimen or sputum culture identified as *M.tb* or *M.tb* complex;

2. Cavitary lesions on chest x-ray or computed tomography scan with respiratory symptoms; or

3. Pulmonary or extra-pulmonary TB in children 10 years of age or less.

(e) The public health nurse case manager for an index case shall mail any TB-41 form to the Department's TB Program at New Jersey Department of Health and Senior Services, TB Program, PO Box 369, Trenton, NJ 08625-0369.

(f) Public health nurse case managers in health jurisdictions other than that in which the index case lives shall:

1. Assist the public health nurse case manager of the index case in the identification, evaluation and final disposition of contacts associated with the index case; and

2. Submit the results of these activities to the public health nurse case manager in the index case's jurisdiction of residence for coordination and submission to the Department's TB Program.

(g) If the index case has contacts outside New Jersey, the Department's TB Program shall assist in securing information regarding the identification, evaluation and final disposition of contacts and provide this information to the public health nurse case manager in the index case's health jurisdiction of residence.

(h) Any health care provider that is evaluating and/or treating contacts to a TB index case meeting the criteria set forth in (d)1 through 3 above shall report the evaluation results and final disposition to the public health nurse case manager upon request.

(i) A health care provider who is not working for a public health clinic shall report verbally to the Department's TB Program at (609) 588-7522 whenever any patient with suspected or confirmed infectious or potentially infectious TB disease misses two consecutive appointments for medical assessment.

1. The report shall include the name of the patient, date of birth, residence address, date of last medical assessment, dates of missed appointments and if the

provider wishes to retain medical supervision or transfer supervision to the public health clinic.

2. The health care provider may submit the report to an appropriate designee of the Department.

i. Health care providers may call the Department's TB Program to determine the appropriate local designee.

(j) The administrator of a hospital shall report to the TB Program at (609) 588-7522 within 24 hours any inpatient with suspected or confirmed infectious or potentially infectious TB disease posing an immediate or imminent public health risk as defined in this subchapter.

(k) The administrator of a hospital shall report the proposed discharge date of a patient with suspected or confirmed infectious or potentially infectious TB disease regardless of time on treatment or smear status to the TB Program at (609) 588-7522 on the last business day that is at least 48 hours prior to the planned discharge date.

1. The hospital shall delay discharge if the administrator cannot achieve this timeline.

2. The report shall include the inpatient's name, address, contact phone number and proposed date of discharge.

(l) The administrator of a correctional facility shall report the release of an inmate with suspected or confirmed infectious or potentially infectious TB disease to the TB Program at (609) 588-7522 at least two working days in advance of the

release, if anticipated, or within one working day of the date of release, if unanticipated.

1. The report shall include the inmate's name, address, contact phone number and date of release.

(m) An administrator, health care provider or nurse case manager may delegate the reporting requirements in N.J.A.C. 8:57-5.4 to a subordinate, but such delegation does not transfer responsibility for adherence to the reporting requirements.

(n) Failure to comply with the reporting requirements established at N.J.A.C. 8:57-5.4 shall subject required reporters to the penalties set forth at N.J.A.C. 8:57-5.18.

(o) No person who reports patient information in order to comply with this subchapter shall be subject to civil, administrative, disciplinary or criminal liability.

8:57-5.5 Hospital discharge

(a) A health care provider managing a patient with suspected or confirmed infectious or potentially infectious TB disease in a hospital may discharge the patient upon meeting one of the following criteria:

1. The patient has an established private residence verified as valid and stable by the public health department and this residence is not shared by any

individual in a vulnerable population, unless it is known that this individual has latent TB infection;

2. Tuberculosis is ruled out as a cause of disease;

3. The patient is a resident of a congregate living facility, is homeless or reports a private residence that the public health department has not verified as valid and stable, and had sputum smears initially positive for AFB; or

i. The patient must have three consecutive sputum smears negative for AFB collected at least eight hours apart; or

ii. The patient must have a nucleic acid amplification test negative for *M. tuberculosis*; or

iii. The patient must have at least one sputum culture negative for *M.tuberculosis* after initiation of appropriate anti-tuberculosis treatment; or

iv. The Department's TB Program may grant an exception based upon clinical evidence and interview of the patient.

4. The patient is a resident of a congregate living facility, is homeless or has reported a private residence that the public health department has not verified as valid and stable, and has no sputum smears positive for AFB, and has been on appropriate anti-TB medications for a period of at least two weeks and has no respiratory symptoms.

(b) The Department's Division of Health Facilities Evaluation and Licensing may investigate a hospital's discharge of a patient who does not meet one of the criteria set forth at (a)1 through 4 above.

1. Any hospital that fails to discharge a patient in accordance with (a)1 through 4 above may be subject to penalties for licensure violations as identified by the Department's Division of Health Facilities Evaluation and Licensure.

8:57-5.6 Health officer responsibilities

(a) Each health officer shall make available a health care provider for medical evaluation and management services for each patient with suspected or confirmed TB disease and latent TB infection in his or her jurisdiction.

1. A health officer may satisfy this requirement through existing staff, contractual arrangement or Memorandum of Agreement with a public health TB clinic.

(b) Any health care provider providing medical management and treatment to residents of New Jersey with suspected or confirmed TB disease or latent TB infection shall provide these services in accordance with the MMWR Treatment of Tuberculosis as set forth at N.J.A.C. 8:57-5.2(a).

1. A health care provider may also use the Department's Standards of Care for Tuberculosis Disease and Latent TB Infection, (hereinafter TB Standards of Care) as guidance for the appropriate medical management of patients with suspected or confirmed TB disease or latent TB infection.

i. TB Standards of Care is available by written request to the Communicable Disease Service, Public Health Services Branch, New Jersey

Department of Health and Senior Services, PO Box 369, Trenton, NJ 08625-0369 or online at http://www.state.nj.us/health/cd/tbhome.htm, then click on Standards of Care.

(c) Each health officer shall make available public health nurse case management services for each patient with suspected or confirmed TB disease, identified contacts, and class B1 or B2 referrals in his or her jurisdiction.

1. A health officer may satisfy this requirement through existing staff, contractual arrangement or Memorandum of Agreement with a public health TB clinic.

(d) Each health officer shall make available field services for each patient with suspected or confirmed TB disease, identified contacts, and class B1 or B2 referrals in his or her jurisdiction.

1. A health officer may satisfy this requirement through existing staff, contractual arrangement or Memorandum of Agreement with a public health TB clinic.

(e) The Department's TB Program shall make verbal translation services accessible to public health clinics, public health nurse case managers and field staff serving patients with TB disease or latent TB infection to overcome communication barriers with the non-English speaking patient population.

8:57-5.7 Notification of precautions to protect the public health

(a) The public health nurse case manager or designee within the health jurisdiction of residence of any patient with a sputum smear positive for AFB or

cavitary lesions on chest radiograph or computed tomography scan with respiratory symptoms shall notify the patient verbally and in writing of the infection control measures required to protect the public health within three working days of the receipt of an initial TB-70 form.

(b) If the patient described in (a) above is hospitalized outside the health jurisdiction of his or her residence, the public health nurse case manager or designee in the health jurisdiction where the patient is hospitalized shall deliver the notification as set forth in (a) above within three working days of being informed of the patient's presence in the facility, regardless of patient's health jurisdiction of residence.

(c) The notification described in (a) and (b) above shall list all infection control measures applicable to the patient, and shall request the patient to observe these infection control measures until no longer necessary to protect the public health.

1. Infection control measures shall no longer be required when a person with sputum smear(s) reported positive for AFB initially has:

i. Three sputum smears reported negative for AFB collected at least eight hours apart; or

ii. A nucleic acid amplification test negative for *M. tuberculosis*; or

iii. At least one sputum culture reported negative for *M.tuberculosis*; or

iv. TB is ruled out as a cause of disease by a health care provider.

2. Infection control measures shall no longer be required in the case where no sputum was collected or all sputum smears were reported by a laboratory as negative for AFB, but the patient had cavitary lesions on chest radiograph or computed tomography scan with respiratory symptoms if:

i. The patient has taken at least two weeks of appropriate treatment and no respiratory symptoms are observed; or

ii. TB has been ruled out as a cause of disease by a health care provider.

(d) The public health nurse case manager in the patient's health jurisdiction of residence shall inform the patient previously required to comply with infection control measures within one business day of when infection control measures are no longer required.

(e) The health officer or designee in the patient's health jurisdiction of residence shall serve the patient required to comply with infection control measures with either a health officer order for isolation established at N.J.A.C. 8:57-5.11, or health officer order for temporary commitment established at N.J.A.C. 8:57-5.12, whichever is necessary to protect the public health within one business day of any refusal to comply with or violation of infection control measures.

1. The health officer or designee in any health jurisdiction shall serve a health officer order as described in (e) above if the patient required to comply with infection control measures is located in his or her health jurisdiction.

8:57-5.8 Diagnostic evaluations

(a) The designated public health nurse case manager for the health jurisdiction of residence shall monitor and facilitate timely diagnostic evaluation of all patients with suspected or confirmed infectious or potentially infectious TB disease, identified contacts to these patients and Class B1 or B2 referrals, regardless of the type of health care provider.

(b) Where a health care provider, based on direct observation or other written clinical and/or laboratory findings, believes that a patient has suspected or confirmed infectious or potentially infectious TB disease, the health care provider shall schedule an appointment for a diagnostic evaluation in his or her office or by referral within five business days of such observation.

(c) The public health nurse case manager shall schedule a diagnostic evaluation in the public health clinic within ten working days after notification of discharge of a New Jersey resident with suspected or confirmed infectious or potentially infectious TB disease from a hospital or correctional facility inside or outside New Jersey, if the patient will be managed by a public health TB clinic.

(d) The public health nurse case manager shall schedule any contact or Class B1 or B2 referral identified or located during an investigation for a diagnostic evaluation in the public health clinic within 20 working days after identification or notification by the Department's TB Program of his or her residence in the public health nurse case manager's health jurisdiction.

(e) A diagnostic evaluation for a person with suspected or confirmed infectious or potentially infectious TB shall consist of at least a physical examination including visual acuity testing, a chest x-ray, sputum collection or induction and laboratory testing.

1. The health care provider may utilize the Department's TB Standards of Care as a guideline for appropriate practice.

(f) A diagnostic evaluation of a contact or Class B1 or B2 referral shall consist of at least a Mantoux tuberculin skin test or an interferon gamma release assay, and a chest x-ray if the skin test is considered significant or the interferon gamma release assay is positive.

1. If active TB disease is suspected based on the results of the diagnostic evaluation, the health care provider shall complete the requirements at (e) above.

2. The health care provider may utilize the Department's TB Standards of Care as a guideline for appropriate practice.

8:57-5.9 Directly Observed Therapy (DOT)

(a) Health care providers may prescribe DOT as a method to monitor the adherence of a patient to his or her prescribed treatment for tuberculosis disease.

1. Health care providers may utilize the Department's TB Standards of Care as a guideline for appropriate utilization of DOT.

(b) Only the patient's health care provider shall have the authority to order or discontinue DOT.

1. If a health care provider discontinues an order for DOT:

i. Any health officer requiring DOT shall be immediately rescinded; and

ii. The health officer who petitioned the Superior Court for court ordered DOT, shall request that the court order be rescinded.

(c) The local health officer in the patient's health jurisdiction of residence shall ensure the provision of DOT as ordered by a health care provider by providing field services as established at N.J.A.C. 8:57-5.6.

1. The provision of DOT on a daily, twice weekly or three times weekly basis shall continue until discontinued by the health care provider.

(d) The designated public health nurse case manager or designee for the health jurisdiction of the patient's residence shall negotiate a time and place to provide DOT.

1. The patient may request reasonable amendment to an established DOT schedule or location from the public health nurse case manager or designee.

2. The public health nurse case manager or designee shall consider the patient's needs and the availability of resources in determining whether to make any accommodation.

(e) The public health nurse case manager shall intervene pursuant to N.J.A.C. 8:57-5.10 if a patient is not at least 80 percent adherent to a prescribed DOT regimen over any one month period throughout the duration of treatment.

8:57-5.10 Management of non-adherent patients requiring a diagnostic evaluation or DOT

(a) This section is applicable to patients with suspected or confirmed infectious or potentially infectious TB disease, identified contacts and Class B1 or B2 referrals that require a diagnostic evaluation to determine their TB status.

1. A public health nurse case manager, when issuing a public health warning notice to a patient, shall seek a diagnostic evaluation on the patient to assess his or her TB status to adequately protect the public health.

2. A health officer, when issuing a health officer order to a patient, shall require a diagnostic evaluation of the patient to assess his or her TB status to adequately protect the public health.

i. A health officer order for diagnostic evaluation of a contact to a patient with suspected or confirmed infectious or potentially infectious TB disease or Class B1 or B2 referral shall remain in force until a diagnostic evaluation is completed and infectious or potentially infectious TB disease is ruled out by a health care provider.

ii. A health officer order for diagnostic evaluation of a patient with suspected infectious or potentially infectious TB disease shall remain in force until infectious or potentially infectious TB disease is ruled out by a health care provider.

iii. A health officer order for diagnostic evaluation of a patient determined by a health care provider to have infectious or potentially infectious TB disease shall remain in force until treatment is completed as determined by a health care provider.

3. A health officer, when initiating a commitment hearing on a patient, shall require a diagnostic evaluation of the patient to assess his or her TB status to adequately protect the public health.

(b) This section is also applicable to persons with suspected or confirmed infectious or potentially infectious TB disease who are non-adherent with prescribed TB treatment recommendations.

1. A public health nurse case manager, when issuing a public health warning notice to a patient, shall seek DOT to monitor adherence with prescribed treatment to protect the public health.

2. A health officer, when issuing a health officer order to a patient, shall require DOT to monitor adherence with prescribed treatment to protect the public health.

i. A health officer order for DOT of a patient with suspected or confirmed infectious or potentially infectious TB disease shall remain in force until either DOT is discontinued by a health care provider or treatment is completed as determined by a health care provider.

3. A health officer, when initiating a commitment hearing on a patient, shall require DOT to monitor adherence with prescribed treatment to protect the public health.

(c) If a public health warning notice or health officer order is made pursuant to N.J.A.C. 8:57-5.10, the health officer or designee shall serve the notice or order by certified mail, return receipt requested or by hand delivery.

1. Successful hand delivery shall include a face-to-face encounter with the patient.

2. Hand delivery by the public health nurse case manager or health officer or designee is preferred, because receipt is witnessed and conditions can be discussed with the patient.

3. The public health nurse case manager, health officer or designee, depending upon who had the face-to-face encounter shall document clearly in the patient's medical record the date and time of the encounter and the patient's response to the conditions of the notice or order.

(d) A health officer order issued pursuant to this section authorizes local law enforcement officers to assist the health officer or designee in hand delivery of the order upon request of the health officer in accordance with N.J.S.A. 26:1A-9.

(e) A public health nurse case manager or designee in the patient's health jurisdiction of residence shall issue a public health warning notice, as set forth at N.J.A.C. 8:57-5.10, to a person identified in (a) or (b) above within two business days of when the patient:

1. Misses two consecutive scheduled appointments;

2. Falls below a medication adherence rate of 80 percent on a treatment regimen of DOT over a one month period; or

3. Refuses diagnostic evaluation or DOT.

(f) The public health warning notice shall:

1. State the nature of the non-adherence;

2. Require the patient to contact the health care provider or clinic indicated in the notice within three business days of receipt of the notice to schedule an appointment for diagnostic evaluation or begin or resume a treatment regimen of DOT whichever is applicable;

3. State the consequences of not satisfying the conditions of the notice; and

4. Be copied and filed in the patient's medical record by the public health nurse case manager or designee.

(g) If the patient described in (e) above fails to meet the conditions of the public health warning notice, the public health nurse case manager shall notify the health officer of the patient's health jurisdiction of residence within two business days of this failure to request a health officer order.

1. If the person is institutionalized or hospitalized, the health officer in the health jurisdiction where the institution or hospital is located shall issue the order.

(h) The health officer shall issue a health officer order within three business days of request by the public health nurse case manager.

(i) The health officer order shall:

1. State the nature of the non-adherence;

2. State the public health consequences of continued non-adherence;

3. Require the patient to contact the health care provider or clinic indicated in the order to schedule an appointment for diagnostic evaluation or begin or

resume a treatment regimen of DOT within three working days of receipt of the order; and

4. State the consequences of not satisfying the conditions of the order.

(j) The public health nurse case manager or designee shall copy and file the health officer order for diagnostic evaluation or DOT in the patient's medical record.

(k) The health officer that issued the order may petition the Superior Court for commitment of the patient violating the order for diagnostic evaluation or DOT pursuant to the hearing process established at N.J.A.C. 8:57-5.14, if the conditions of a health officer order are not met within three business days.

1. The health officer is required to consult with the Department's TB Program or State Epidemiologist or designee before petitioning the Superior Court.

(l) If at any time during the intervention process described in (e) through (k) above the patient becomes adherent, the process shall be immediately interrupted.

1. If the patient with suspected or confirmed infectious or potentially infectious TB disease becomes non-adherent again prior to the completion of treatment, the intervention process shall resume at whatever step was next applicable when the patient became adherent.

8:57-5.11 Management of non-adherent patients through a health officer order for isolation

(a) Pursuant to N.J.S.A 26:4-2, the health officer in the patient's jurisdiction of residence may exclude a patient posing an immediate or imminent risk to the public health from attending his or her place of work or school, or other premises where the health officer determines that such action is necessary to protect the public health.

1. The health officer shall consult with the Department's TB Program or State Epidemiologist or designee is required before excluding a patient from a workplace, school or other premises through a health officer order.

2. In no case shall a health officer exclude a patient from a workplace, school or other premises for more than 60 days without a court order authorizing such exclusion pursuant to the hearing process established at N.J.A.C. 8:57-5.14.

(b) If a patient excluded from a workplace or school or other premises, pursuant to N.J.S.A. 26:4-2, requests a review of the health officer order, the health officer that issued the order shall make application for a court order authorizing such exclusion within five business days from the date of the request.

1. After any such request, exclusion shall not continue for more than ten business days without a court order pursuant to the hearing process established at N.J.A.C. 8:57-5.14.

(c) The health officer in the patient's health jurisdiction of residence shall issue a health officer order for isolation within two working days of when the

patient meets the definition of immediate or imminent risk to the public health, but is not a risk for flight.

1. If the patient is institutionalized or hospitalized, the health officer in the jurisdiction where the institution or hospital is located shall issue the order.

2. If the patient has suspected or confirmed infectious or potentially infectious TB disease, is suspected or confirmed to have either MDR-TB or XDR-TB, and is non-adherent or threatens non-adherence with infection control measures regardless of his or her risk for flight, the health officer shall serve the patient an order of temporary commitment pursuant to N.J.A.C. 8:57-5.12 rather than an order for isolation due to the severity of the consequences of transmission.

(d) The health officer order shall:

1. State the reason for the order;

2. Reiterate the infection control measures necessary to protect the public health;

3. State the conditions that must be met for the order to be lifted; and

4. State the consequences of violating the order.

(e) The public health nurse case manager or designee shall copy and file the health officer order for isolation in the patient's medical record.

(f) If a health officer order is made pursuant to N.J.A.C. 8:57-5.10, the health officer or designee shall hand deliver the order.

1. Successful hand delivery requires a face-to-face encounter with the patient.

2. The health officer or designee, depending upon who had the face-to-face encounter shall document the date and time of the encounter and the patient's response to the conditions of the order in the medical record.

(g) A health officer may request local law enforcement officers to exercise their authority to assist the health officer or designee in hand delivery of the health officer order in accordance with N.J.S.A. 26:1A-9.

(h) If the patient violates the conditions of the order, the health officer that issued the order may petition the Superior Court for commitment of the patient for the protection of the public health pursuant to the hearing process established at N.J.A.C. 8:57-5.14.

1. The health officer shall consult with the Department's TB Program or the State Epidemiologist or designee before petitioning the Superior Court.

(i) If the health officer seeks court commitment, the Commissioner or State Epidemiologist or designee, in consultation with the health officer and the Department's TB Program, shall designate the least restrictive appropriate placement for the patient during the period of commitment.

1. This may be an acute care facility or private residence.

2. If the location of commitment is a private residence, law enforcement may use an electronic device to monitor adherence to the commitment order.

(j) The health officer in (c) above may immediately petition the Superior Court for commitment if the patient at any time during the course of treatment

again poses an immediate or imminent public health risk and violates the conditions set forth in a health officer order for isolation.

8:57-5.12 Management of non-adherent patients through health officer order for temporary commitment

(a) If the Commissioner or State Epidemiologist or designee or the health officer in the patient's health jurisdiction of residence determines that the patient is not only an immediate or imminent risk to the public health, but also a risk for flight, the health officer shall immediately order the temporary commitment of the patient to the site designated by the Commissioner or State Epidemiologist or designee, pending an expedited commitment hearing before the Superior Court.

1. The health officer in the jurisdiction where the institution or hospital is located shall issue the order if the person is institutionalized or hospitalized.

2. If the patient has suspected or confirmed infectious or potentially infectious TB disease, is suspected or confirmed to have either MDR-TB or XDR-TB, and is non-adherent or threatens non-adherence with infection control measures, regardless of his or her risk for flight, the health officer shall immediately serve the patient an order of temporary commitment pursuant to N.J.A.C. 8:57-5.12 rather than an order for isolation due to the severity of the consequences of transmission.

(b) Under no circumstances shall a health officer order for temporary commitment remain in force for more than 30 days without a court order

authorizing such commitment pursuant to the hearing process established at N.J.A.C. 8:57-5.14.

(c) The health officer order for temporary commitment shall:

1. State the reason for the order;

2. State the site of commitment;

3. State the conditions of commitment; and

4. State that a Superior Court Hearing will occur within the next 30 days or the order will be rescinded.

(d) A health officer order for temporary commitment shall be hand delivered to the effected person by the health officer or designee.

(e) The health officer shall notify the subject of the order for temporary commitment of the date and time of the Superior Court hearing at least two days in advance.

(f) In the circumstance described in (a) above and in accordance with N.J.S.A. 26:1A-9, local law enforcement officers are authorized to take the patient into custody and place him or her at the location designated by the Commissioner or State Epidemiologist or designee and monitor or ensure that the patient remains at that location until the hearing date and that the patient is available for the hearing.

1. If the appropriate placement is determined to be a residence, law enforcement may use an electronic device to enforce temporary commitment.

(g) If the health officer in the patient's health jurisdiction of residence seeks the assistance of local law enforcement officers, the health officer shall provide the following information (as applicable) to law enforcement:

1. The order under which temporary commitment is authorized;

2. The site where temporary commitment will be served;

3. The name, address or last known location, a picture, if available, and the skin color, hair color, height, weight, and age of the patient, any tattoos or scars that could assist in identification; and

4. The date and time of the expedited commitment hearing.

(h) The health officer that issued the order for temporary commitment shall seek the assistance of local legal counsel to prepare the petition for commitment by the Superior Court.

8:57- [5.7] 5.13 Grounds for commitment

(a) In accordance with N.J.S.A. 30:9-57, the Commissioner [, Department of Health and Senior Services, or his or her designee,] or local health officer in consultation with the [Manager of the] TB Program and/or the State Epidemiologist or designee, may [make application in] petition the Superior Court [of New Jersey] for an Order of Commitment [in those instances where:

1. A person in any of the following categories has clearly expressed refusal to comply, or has failed to comply, with the diagnostic examination requirements as set forth at N.J.A.C. 8:57-5.5: a person with clinically active

tuberculosis, a person who is a close contact to either an active or clinically suspected active tuberculosis case, or a person with TB infection and active TB has not been ruled out;

2. A person with active or clinically suspected active tuberculosis has not complied with an order for DOT. Compliance is defined as taking 80 percent of the prescribed medication;

3. A person with active or clinically suspected active TB is unable or unwilling to comply with a prescribed treatment regimen and/or infection control requirements;

4. A person with infectious MDR-TB is unable or unwilling to comply with infection control requirements; or

5. The Commissioner, or his or her designee, has determined that the public health, or the health of any other person, is endangered by an active or clinically suspected active case of TB] whenever a patient violates:

1. A health officer order for diagnostic evaluation or DOT issued pursuant to N.J.A.C. 8:57-5.10;

2. A health officer order for isolation issued pursuant to N.J.A.C. 8:57-5.11; or

3. A health officer order for temporary commitment issued pursuant to N.J.A.C. 8:57-5.12.

(b) The health officer, Commissioner, State Epidemiologist or designee shall petition the Superior Court for an expedited hearing to consider commitment

whenever a health officer has issued an order for temporary commitment to a patient pursuant to N.J.A.C. 8:57-5.12.

[(b)](c) [Persons sought to be committed] The health officer, Commissioner, State Epidemiologist or designee shall advise patients for whom he or she is seeking commitment under this section [shall be advised] of [these reasons] the reason for the proposed commitment and shall [be granted] grant an opportunity for a hearing, as set forth at N.J.A.C. 8:57- [5.8] 5.14 and [5.9] 5.15.

8:57-5.14 Hearing process

(a) In accordance with N.J.S.A. 30:9-57, the health officer, Commissioner, State Epidemiologist, or designee shall inform the patient to be committed of his or her right to a hearing in the Superior Court.

1. The health officer or designee shall serve the patient considered for commitment a copy of the applicable rules, the reasons for the proposed commitment and notice of the time and place of the hearing at least two days prior to the hearing.

(b) If the Superior Court finds the patient described in (a) above committable, the health officer, Commissioner, State Epidemiologist or designee shall commit the patient to a hospital or private residence designated by the Commissioner, State Epidemiologist or designee.

(c) In no event shall the health officer, Commissioner, State Epidemiologist or designee commit any patient for more than 90 days from the

date of the original court order for commitment without seeking further court review.

1. The health officer, Commissioner, State Epidemiologist, or designee shall seek further court review within 90 days of each subsequent court order if the patient continues to pose an immediate or imminent risk to the public health.

(d) If the patient's risk to the public subsides during the 90 day commitment period, the health officer, Commissioner, State Epidemiologist or designee may inform the court and seek an order rescinding the commitment order.

(e) If the location where commitment will be served is a private residence, law enforcement may enforce adherence to the commitment order by electronic device.

(f) The health officer, Commissioner, State Epidemiologist, or designee shall report to the Superior Court any violation of a court order for commitment.

8:57- [5.9] 5.15 Due process

(a) (No change.)

8:57- [5.13] 5.16 Annual report

The Manager of the TB Program shall submit to the Commissioner and make available to the public, through the TB Program's website at http://nj.gov/health/cd/tbhome.htm, an annual report describing trends in

prevalence and incidence of TB [and MDR-TB] in New Jersey. [The report shall also include descriptive statistics showing the frequency and trends of those reportable events set forth at N.J.A.C. 8:57- 3. The first report shall be issued 12 months after the effective date of these rules and subsequent reports shall be due annually thereafter.]

8:57- [5.14] 5.17 Confidentiality of [records] information

(a) (No change.)

(b) [Violation of (a) above may result in penalties as provided for at N.J.A.C. 8:57-5.16] The reports and forms submitted to the Department pursuant to N.J.A.C. 8:57-5 contain demographic and medical information related to the Department's investigations and epidemiological studies of TB and shall not be considered "government records" subject to public access or inspection within the meaning of N.J.S.A. 47:1A-1 et seq. and shall be deemed:

1. "Information relating to medical … history, diagnosis, treatment, or evaluation" within the meaning of Executive Order 26, §4(b)1 (McGreevey, August 13, 2002); and/or

2. "Records concerning morbidity, mortality, and reportable diseases of named persons required to be made, maintained or kept by any State or local governmental agency" within the meaning of Executive Order 9, §2(c) (Hughes, September 30, 1963); and /or

3. Information "for use in the field of forensic pathology or for use in medical or scientific education or research" pursuant to N.J.S.A. 47:1A-1.1.

[8:57-5.15 Mandatory exclusion from workplace or school

(a) Pursuant to N.J.S.A. 26:4-2, the local health officer may order that a person with known or clinically suspected active tuberculosis be excluded from attending his or her place of work or school, or be excluded from other premises where the local health officer determines, after a review of the facts and circumstances of the particular case, that such an action is necessary to protect the public health.

(b) If a person excluded from a work place or school, pursuant to N.J.S.A. 26:4-2, requests a review of the order, the local health officer shall make an application for a court order authorizing such exclusion within five business days after such request. After any such request, exclusion shall not continue more than 10 business days without a court order. In no case shall a person be excluded from a workplace, school, or other premises for more than 60 days without a court order authorizing such exclusion. The local health officer shall seek further court review of such exclusion within 90 days of the original court order or each subsequent court order.

(c) In any court proceeding under (b) above, the local health officer shall prove each required element for such exclusion by clear and convincing evidence.

(d) The elements for an order for exclusion issued by a local health officer under this section are:

1. Documentation of medical evidence indicating the presence of known or clinically suspected active tuberculosis and an assessment of the person's medical condition;

2. An individualized assessment of the person's circumstances and/or behavior constituting the basis for the issuance of the order; and

3. The less restrictive alternatives that were attempted and/or the less restrictive alternatives that were considered and rejected, and the reasons such alternatives were rejected.

(e) The local health officer shall rescind the order for exclusion upon documentation by a health care provider that the patient had three negative bacteriological smears at clinically appropriate intervals and a significant reduction of clinical symptoms. The local health officer may seek independent review by another health care provider if he or she has reason to doubt the primary health care provider's determination.]

8:57- [5.16] 5.18 Penalties for violation of rules

[Any person who fails to adhere to any provision of this subchapter shall be subject to a fine of $50.00 each day for the first offense and $100.00 each day for the second and any subsequent offenses. All violations by health care

providers shall be reported to the appropriate professional licensing authorities and public financing programs.]

(a) A health care provider who fails to comply with the requirements of this subchapter shall be subject to a fine as set forth at N.J.S.A. 26:4-129 and 4-130, or N.J.S.A 26:1A-10.

1. The Department may issue a written notification of this failure and a warning to comply prior to initiating any other enforcement action.

2. The Department may also report the health care provider's failure to comply with the provisions of this subchapter to the New Jersey Board of Medical Examiners which may initiate disciplinary actions as set forth at N.J.A.C. 13:35-6.24.

(b) An administrator of a health care facility who fails to comply with the requirements of this subchapter shall be subject to a fine as set forth at N.J.S.A. 26:4-129 and 4-130, or N.J.S.A. 26:1A-10.

1. The Department may issue a written notification of this failure and a warning to comply prior to initiating any other enforcement action.

2. The Department may also report the health care facility's failure to comply with the provisions of this subchapter to the Department's Division of Health Care Quality and Oversight, which may initiate enforcement actions as set forth at N.J.A.C. 8:43E-3.

(c) A health officer who fails to comply with the requirements of this subchapter shall be subject to a fine as set forth at N.J.S.A. 26:4-129 and 4-130 or N.J.S.A. 26:1A-10.

1. The Department may issue a written notification of this failure and a warning to comply prior to initiating any other enforcement action.

2. The Department may also report the health officer's failure to comply with the provisions of this subchapter to the Department's Public Health Licensing and Examination Board, which may initiate disciplinary actions as set forth at N.J.A.C. 8:7-1.7 and N.J.S.A. 26:1A-43.

(d) A public health nurse case manager who fails to comply with the requirements of this subchapter shall be subject to a fine as set forth at N.J.S.A. 26:4-129 and 4-130 or N.J.S.A. 26:1A-10.

1. The Department may issue a written notification of this failure and a warning to comply prior to initiating any other enforcement action.

2. The Department may also report the public health nurse case manager's failure to comply with the provisions of this subchapter to the Board of Nursing which may initiate disciplinary actions as set forth at N.J.S.A. 45:1-21.

8:57-6.1 [Applicability] Purpose and scope

(a) The purpose of this subchapter is to:

1. Implement the provisions of N.J.S.A. 18A:61D-1 et seq.;

2. Set forth the immunization standards which students entering institutions of higher education shall meet, to reduce the likelihood of outbreaks on institution campuses and related disruption to the academic process; and

3. Reduce the incidence of certain vaccine preventable diseases in the greater community.

[(a)] (b) (No change in text.)

[(b)] (c) (No change in text.)

[(c)] (d) Four year institutions shall apply the rules to all full-or part-time students enrolled in a program leading to an academic degree [.] , except as specified for hepatitis B vaccine at N.J.A.C. 8:57-6.9.

[(d)] (e) Two-year institutions and Thomas Edison State College shall not be required to apply the meningococcal rule at 8:57- [6.6] 6.8 and 8:57- [6.7] 6.10.

8:57-6.2 Incorporated documents

(a) The Department incorporates by reference in this subchapter the Annual College Immunization Status Report form (IMM-3), available in the subchapter Appendix, and through the following methods:

1. For electronic submission at

http://www.nj.gov/health/cd/imm3/annualstatusrpt.shtml;

2. Verbal request to the Department at (609) 588-7512; and

3. Written request mailed to the New Jersey Vaccine Preventable Disease Program, Department of Health and Senior Services, PO Box 369, Trenton, NJ 08625-0369.

8:57- 6.3 Definitions

The following words and terms, as used in this subchapter, shall have the following meanings, unless the context clearly indicates otherwise:

"ACIP" means the Advisory Committee for Immunization Practices for the United States Centers for Disease Control and Prevention.

"Advanced practice nurse" means a nurse practitioner, certified registered nurse practitioner, clinical nurse specialist, or nurse practitioner/clinical nurse specialist.

"Campus dormitory" means a dormitory, residence hall, student housing, or a comparable congregate living arrangement owned, operated or contracted by the institution.

"Institution of higher education" or "institution" means a two or four-year college or university that grants academic degrees.

"Minor" means a person that is less than 18 years of age.

"NJIIS" means the New Jersey Immunization Information System (Immunization Registry) operated by the New Jersey Vaccine Preventable Disease Program within the Department's Public Health Service Branch, Communicable Disease Service and established pursuant to N.J.S.A. 26:4-131 et seq.

"New Jersey Vaccine Preventable Disease Program" means the health program within the Department of Health and Senior Services that is responsible for the implementation, monitoring, and enforcement of the higher education immunization rules.

8:57- [6.2] 6.4 Exemptions

(a) A student shall be exempt from immunization requirements for medical or religious reasons, provided that he or she meets the criteria as set forth at N.J.A.C. 8.57-[6.11] 6.14 and 8:57- [6.12] 6.15, respectively.

(b) In addition, [an exemption may be made, at the discretion of the institution,] an institution may make an exemption for the following categories of students;

1. Students born before 1957 for the measles, mumps, and rubella (MMR) vaccination requirements only; or

2. Students enrolled in a program for which students do not congregate, on campus or in an off-campus facility, whether for classes or to participate in

institution-sponsored events, such as those enrolled in programs for individualized home study or conducted entirely via electronic media.

(c) Nothing in this subchapter shall be construed as limiting the authority of a New Jersey institution of higher education to establish additional requirements for student immunizations and documentation that such institution shall determine appropriate and which is recommended by the [Advisory Committee on Immunization Practices (ACIP) of the United States Public Health Service] ACIP.

8:57- [6.3] 6.5 Required immunization; measles

(a) Each new student entering [college] the institution for the first time after September 1, 1995 shall have received two doses of a live measles-containing vaccine, or any vaccine combination containing live measles vaccine, that was administered after 1968.

1. The first dose shall have been administered on or after the first birthday and the second dose shall have been administered no less than one month after the first dose.

(b) (No change.)

(c) A student who presents documented laboratory evidence of measles immunity shall not be required to receive either the first or second dose of measles vaccine.

(d) The institution shall count measles containing vaccine administered up to four days before the student's first birthday or four days before the one month (28 days) interval to the second dose as a valid dose.

8:57- [6.4] 6.6 Required immunization; mumps

(a) Each new student entering [college] an institution for the first time after September 1, 1995 shall have received one dose of live mumps virus vaccine, or any vaccine combination containing live mumps virus vaccine.

1. The vaccine shall have been administered on or after the student's first birthday.

(b) (No change.)

(c) Institutions shall also count mumps virus containing vaccine administered up to four days before the student's first birthday as a valid dose.

8:57- [6.5] 6.7 Required immunization; rubella

(a) Each new student entering [college] an institution for the first time after September 1, 1995, shall have received one dose of live rubella virus vaccine, or any vaccine combination containing live rubella virus vaccine.

1. The vaccine shall have been administered on or after the student's first birthday.

(b) (No change.)

(c) Institutions shall also count rubella virus containing vaccine administered up to four days before the student's first birthday as a valid dose.

8:57- [6.6] 6.8 Required immunization; meningococcal

(a) Each new student entering a four-year [college or university] institution, for the first time after September 1, 2004 and who resides in a campus dormitory, shall receive one dose of meningococcal vaccine as condition of attendance at that institution, except as provided in N.J.A.C. 8:57- [6.11] 6.14 and [6.12] 6.15.

(b) An institution shall exempt a student from the meningococcal vaccine requirement if the student objects thereto in a written statement submitted to the institution signed by the student or the parent or legal guardian if a minor, explaining how the administration of meningococcal vaccine conflicts with the student's bona fide religious tenets or practices, except that a general philosophical or moral exemption to the vaccination shall not be sufficient for an exemption on religious grounds.

8:57-6.9 Required immunization; hepatitis B

(a) Each new student entering a two or four year institution for the first time on or after September 1, 2008 enrolled with a course study of 12 or more credit hours per semester or term shall have received three doses of a hepatitis B

containing vaccine, or alternatively any two doses of a hepatitis B vaccine licensed and approved for a two dose regimen administered to the student between 11 through 15 years of age.

(b) An institution shall be prohibited from permitting a provisional period of more than nine months to complete the hepatitis B series for each new student entering a two or four institution on or after September 1, 2008 enrolled with a course study of 12 or more credit hours per semester or term and who has not begun or provided documentation of the hepatitis B vaccine series, while remaining in attendance.

(c) An institution shall be prohibited from permitting a new student entering a two or four year institution on or after September 1, 2008 enrolled with a course study of 12 or more credit hours per semester or term and who has one documented dose of a hepatitis B vaccine, from having longer than six months to complete the three dose hepatitis B vaccine series.

(d) An institution shall be prohibited from permitting a new student entering a two or four year institution on or after September 1, 2008 enrolled with a course study of 12 or more credit hours per semester or term and who has presented documentation of two doses of a hepatitis B vaccine, from having longer than four months to complete the hepatitis B vaccine series.

(e) An institution shall not require a student who presents documented laboratory evidence of hepatitis B disease or immunity, constituting a medical exemption, to receive hepatitis B vaccine.

(f) An institution shall exempt a student from the hepatitis B vaccine requirement if the student objects thereto in a written statement submitted to the institution, signed by the student or a parent or legal guardian if a minor, explaining how the administration of hepatitis B vaccine conflicts with the student's bona fide religious tenets or practices, except that a general philosophical or moral exemption to the vaccination shall not be sufficient for an exemption on religious grounds.

8:57- [6.7] 6.10 Required information: Meningococcal disease and meningococcal vaccine

(a) Each new student entering any New Jersey four year [college or university] institution after September 1, 2001, and prior to matriculation, shall be provided information on meningococcal disease to, at a minimum, include its nature and severity, causes, disease prevention and treatments, and the availability of a meningococcal vaccine to prevent disease.

(b) Each student shall receive a response form, or a similar form, from the [college] institution, which documents the receipt of the meningococcal information and their response to the information provided.

(c) Each student not returning the meningococcal response form shall not be subject to the provisional admission requirements set forth at N.J.A.C. 8:57-[6.9(b) and (c)] 6.12(b) and (c).

8:57- [6.8] 6.11 Institutional responsibility for enforcement

(a) All New Jersey institutions of higher education shall require evidence of immunization as a prerequisite to enrollment of all students except those who meet the exemption requirements set forth at N.J.A.C. 8:57- [6.2(b)] 6.4(b), [6.11 and 6.12] 6.14 and 6.15, or those students enrolled in two-year institutions who are registered for fewer than 12 credit hours per semester [/] or term.

(b)–(c) (No change.)

8:57- [6.9] 6.12 Provisional admission

(a) [A student may be registered in an] An institution of higher education may permit a student to register on a provisional basis for his or her first term if the required immunization documentation is not available at the time of registration.

(b) Prior to registration for the second term, a student shall either present documentation of immunization or proof of immunity in accordance with the requirements of this subchapter or be reimmunized[.] , except as provided for hepatitis B vaccine at N.J.A.C. 8:57-6.9(b) through (d).

(c) [A student in provisional status may be temporarily excluded] An institution may temporarily exclude a student in provisional status from classes and from participation in institution-sponsored activities during a vaccine preventable disease outbreak or threatened outbreak.

1. [This] The decision to exclude a student in provisional status shall be made by the institution in consultation with the Commissioner [, Department of Health and Senior Services or his or her designee. This] and the exclusion shall continue until the outbreak is over or until proof of the student's immunization or immunity is furnished.

8:57- [6.10] 6.13 Documents accepted as evidence of immunization

(a) [The following documents shall be accepted] An institution shall accept as evidence of a student's immunization history the following documents provided that the type of immunization and the date when each immunization was administered is listed:

1. An official school immunization record or copy thereof from any primary or secondary school, or institution of higher education, indicating compliance with the immunization requirements set forth at N.J.A.C. 8:57- [6.3] 6.5, [6.4] 6.6, [6.5] 6.7, [and 6.6;] 6.8, and 6.9; or

2. A record from any public health department indicating compliance with the immunization requirements set forth at N.J.A.C. 8:57- [6.3] 6.5, [6.4] 6.6, [6.5] 6.7, [and 6.6;] 6.8, and 6.9; or

3. A record or an official college affidavit form signed by a physician licensed to practice medicine or osteopathy in any jurisdiction of the United States or in any foreign country, an advanced practice nurse (certified registered nurse practitioner or clinical nurse specialist), or any other licensed health professional

approved by the Department [of Health and Senior Services], which indicated compliance with the immunization requirements set forth at N.J.A.C. 8:57- [6.3] 6.5, [6.4] 6.6, [6.5] 6.7, [and 6.6;] 6.8, and 6.9; or

4. An official record of immunization from the New Jersey Immunization Information System (NJIIS) indicating compliance with the immunization requirements of this subchapter; or

5. A military immunization or health record from the United States Armed Forces indicating compliance with the immunization requirements of this subchapter.

8:57- [6.11] 6.14 Medical exemptions

(a) A student shall not be required to have any specific [immunizations(s)] immunizations, which are medically contraindicated.

(b) [A] An institution shall exempt a student from the specific immunization requirements for the stated period of time based on a written statement submitted to the institution [from] by a physician licensed to practice medicine or osteopathy, or an advanced practice nurse (certified nurse practitioner or clinical nurse specialist) in any jurisdiction of the United States, or in any foreign country, indicating that an immunization is medically contraindicated for a specific period of time, and setting forth the reason(s) for the medical contraindication, based upon valid medical reasons as enumerated by [the most recent recommendations of the Advisory Committee on Immunization Practices

(ACIP) of the United States Public Health Service, shall exempt a student from the specific immunization requirements for the stated period of time] the 2007 Advisory Committee on Immunization Practices (ACIP), Recommended Child, Adolescent, and Adult Immunization Schedules and the ACIP Recommendations, available as set forth in (b)1 and 2 below:

[1. The guidelines identified in (b) above are available from the Advisory Committee on Immunization Practices, U.S. Public Health Service, Centers for Disease Control and Prevention, Atlanta, GA 30333.]

1. The 2007 Advisory Committee on Immunization Practices (ACIP), Recommended Childhood, Adolescent, and Adult Immunization Schedules, which is amended yearly, is available through:

i. Verbal request to the Department at (609) 588-7512;

ii. Written request mailed to the New Jersey Vaccine Preventable Disease Program, Department of Health and Senior Services, PO Box 369, Trenton, NJ 08625-0369; or

iii. Online at http://www.cdc.gov/vaccines/recs/schedules/default.htm#child.

2. The applicable ACIP Recommendations pertaining to medical guidelines for each vaccine preventable disease and the relevant preventive vaccine, are available online at http://www.cdc.gov/vaccines/pubs/ACIP-list.htm.

(c) [The] An institution shall retain the physician's or an advanced practice nurse's (certified registered nurse practitioner or clinical nurse specialist) statement [shall be retained] as part of the student's immunization record [and shall be reviewed annually by the institution to determine whether the exemption shall remain in effect for the next year].

1. The institution shall annually review the statement to determine whether the exemption shall remain in effect for the next year.

2. When the student's medical condition permits immunization, [this] the medical exemption shall thereupon terminate and the student shall be required to obtain the immunization(s) from which he or she has been exempted.

(d) [A] An institution may temporarily exclude a student with medical exemptions [to] from receiving specific immunizations, [may be temporarily excluded] from classes and from participating in institution-sponsored activities during a vaccine-preventable disease outbreak or threatened outbreak.

1. [This] The decision to exclude a student with a medical exemption shall be made by the institution in consultation with the Commissioner [, Department of Health and Senior Services or his or her designee. This] and the exclusion shall continue until the outbreak is over or until proof of the student's immunization or immunity is furnished

8:57- [6.12] 6.15 Religious exemptions

(a) A student shall be exempted from mandatory immunization if the student objects thereto in a written statement submitted to the institution , signed by the student or a parent or legal guardian if a minor, explaining how the administration of immunizing agents conflicts with the student's religious beliefs[.]; except as provided at N.J.A.C. 8:57- 6.8(b) and N.J.A.C. 8:57-6.9(f).

(b) [This statement shall be kept by the institution] The institution shall keep the student's statement as part of the student's immunization record.

(c) [A] An institution may temporarily exclude a student with a religious exemption from receiving immunizing agents, [may be temporarily excluded] from classes and from participation in institution-sponsored activities during a vaccine preventable disease outbreak or threatened outbreak.

1. [This] The decision to exclude a student with a religious exemption shall be made by the institution in consultation with the Commissioner [, Department of Health and Senior Services or his or her designee. This] and the exclusion shall continue until the outbreak is over.

8:57-[6.13] 6.16 Institutional records required

(a) All New Jersey institutions of higher education shall maintain records of immunizations on each student in a format either specified or approved by the Department.

1. Each record shall indicate the date of each required immunization, laboratory evidence of immunity, or, where applicable, the requisite documents,

as required pursuant to N.J.A.C. 8:57 - [6.11or 6.12] 6.14 or 6.15 pertaining to any medical or religious exemptions.

(b) All New Jersey institutions of higher education shall maintain immunization records in a manner, which allows accessibility to health officials, yet insures the confidentiality of the student's other records.

1. Student immunization histories may be entered into an institution's secure electronic database.

(c) - (d) (No change.)

(e) All New Jersey institutions of higher education shall, upon request, [of a student] release to a student his or her immunization records or an authenticated electronic printout of that record.

1. Requests for such records shall be honored for three years following a student's graduation, termination, transfer, or departure from the institution.

8:57-[6.14] 6.17 Reports to be submitted to the Department of Health and Senior Services.

(a) [A report of the immunization status of students in every institution shall be sent] Each institution shall provide a report of the immunization status of students each year to the Department [of Health and Senior Services.] using the Annual College Immunization Status Report (IMM-3), available in the subchapter Appendix.

1. [This report shall be submitted by the] The official designated pursuant to N.J.A.C. 8:57- [6.8(b)] 6.11(b) to be responsible for the administration and enforcement of this subchapter and for the maintenance of immunization records shall submit the report through the mail or submit electronically, through the addresses set forth in N.J.A.C. 8:57-6.2 (a).

[(b) The form for the annual immunization status report shall be provided by the Department of Health and Senior Services.]

[(c)](b) The [report] institution shall document the total number of students who are specifically covered by the applicable education or vaccination requirements of this subchapter relevant to that institution, the number of students who are vaccinated, the number of students in provisional status, the number of students with medical exemptions, the number of students with religious exemptions, and the number of students not receiving the required immunizations.

[(d)](c) The [report shall be submitted by December 1 of the academic year which begins in September of the same year after the review of all appropriate immunization records.] institution shall submit the Annual College Immunization Status Report by December 1 of the academic year which begins in September of the same year after the review of all appropriate immunization records.

[(e)](d) Each four-year institution of higher education shall [also submit an] complete the [annual] meningococcal section of the Annual College Immunization Status report [provided by the Department of Health and Senior

Services] by December 1, for each academic year which begins in September of the same year.

[(f)](e) The annual meningococcal section of the Annual College Immunization Status report from each four year institution shall document, at a minimum, the total number of new students, the number of students' responses received, and the number of new students vaccinated.

8:57-[6.15] 6.18 Records available for inspection

(a) All institutions shall maintain centralized records of their students' immunization status.

1. Upon 24 hours notice, those records shall be made available for inspection by authorized representatives of the Department [of Health and Senior Services] or the local board of health in whose jurisdiction the institution of higher education is located.

8:57-[6.16] 6.19 Providing immunization

(a) Each institution may administer the vaccines required by, or referred to within this subchapter for [these] students who are unable to obtain vaccine documentation or obtain the measles, mumps, rubella, hepatitis B, or meningococcal vaccines from their own health providers.

(b) (No change.)

(c) Each two and four-year institution shall offer the hepatitis B vaccine through the institution's student health service or by a contractual agreement with a community health care provider.

8:57-[6.17] 6.20 Reporting requirements

Each New Jersey institution of higher education shall report the suspected presence of any reportable communicable disease, as identified at N.J.A.C. 8:57-[1.3] 1.5 and N.J.A.C. 8:57-[1.4] 1.6 to the local health officer having jurisdiction over the locality in which such institution is located.

8:57-[6.18] 6.21 Modifications in the event of an outbreak or vaccine shortage

(a) In the event of an outbreak or threatened outbreak, the Commissioner [, Department of Health and Senior Services, his or her designee,] or local health officers may modify the immunization requirements as set forth in this subchapter to meet the emergency.

1. These modifications may include obtaining immunization documentation or requiring specific immunizations for each student not covered by this subchapter.

2. Each student failing to meet these additional requirements may be temporarily excluded from classes and from participating in institution sponsored activities.

3. This exclusion shall continue until the outbreak is over or until proof of the student's immunization or immunity is furnished.

(b) In the event of a national or State vaccine shortage as determined by the Centers for Disease Control and Prevention (CDC) and Commissioner respectively, the Commissioner or his or her designee may temporarily suspend the immunization requirement for the particular vaccine affected by the supply shortage after provision of notice to the public, such as through any of the methods below:

1. Electronic posting on the Department's website;

2. Print and electronic media;

3. The Department's Local Information Network and Communications System (LINCS);

4. The Department's Vaccine Preventable Disease Program; or

5. Any other method reasonably calculated to inform those persons or institutions most likely to be affected by or interested in the temporary immunization requirement suspension.

8:57-7 (No change.)

8:57-8.1 Purpose and scope

(a)-(b) (No change.)

8:57-8.2 Incorporated documents

(a) The Department incorporates by reference the following documents in this subchapter:

1. The 2007 Advisory Committee on Immunization Practices (ACIP), Recommended Childhood and Adolescent Immunization Schedule, as amended and supplemented, which is available online at www.cdc.gov/vaccines/recs/schedules/default.htm#child or from the U.S. Department of Health and Human Services, Centers for Disease Control and Prevention as published in the Morbidity and Mortality Weekly Report, as amended from time to time, which can be obtained from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402, telephone (202) 512-1800.

2. The applicable "ACIP Recommendations" pertaining to each licensed vaccine and its utilization to prevent certain vaccine preventable diseases, which are available online at the Centers for Disease Control and Prevention's Vaccines and Immunizations website at: www.cdc.gov/vaccines/pubs/ACIP-list.htm.

8:57- [8.2] 8.3 Definitions

The following words and terms, as used in this subchapter, shall have the following meanings, unless the context clearly indicates otherwise:

. . .

["Commissioner" means the Commissioner of the New Jersey Department of Health and Senior Services.]

"DTaP" means a combined vaccine which includes toxoids and antigens to prevent diphtheria, tetanus and a more purified antigenic component of the [Bordetalla] *Bordetella pertussis* (acellular pertussis) to prevent pertussis disease, and which may also reduce the likelihood of an adverse vaccine reaction.

. . .

"Hepatitis A" means a vaccine containing antigens to protect against hepatitis A disease.

. . .

"NJ FamilyCare" means a program of the Department of Human Services that provides health insurance for financially eligible children and families.

. . .

"Pneumococcal vaccine" means a vaccine which contains antigens to prevent the occurrence of pneumonia in certain healthy and high risk populations[.] , and includes pneumococcal conjugate vaccine or the pneumococcal polysaccharide vaccine.

. . .

"Tdap" means a combination vaccine, which contains tetanus and reduced diphtheria toxoids and acellular pertussis antigens used as a booster vaccination to protect against diphtheria, tetanus, and pertussis diseases.

. . .

8:57- [8.3] 8.4 Immunizations that must be covered

(a) (No change.)

(b) A carrier shall provide services or benefits for:

1. Immunizations [which are] specified in the 2007 Recommended Childhood and Adolescent Immunization Schedule, and described in the ACIP Recommendations, as set forth at N.J.A.C. 8:57-8.2(a) [published by the U.S. Department of Health and Human Services, Centers for Disease Control and Prevention in the Morbidity and Mortality Weekly Report, as amended from time to time, which can be obtained from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402, telephone (202) 512-1800]; and

2. All routine childhood vaccines as specified in the " 2007 Recommended Childhood and Adolescent Immunization Schedule," and as described in the ACIP Recommendations:

i.-v. (No change.)

3. Such immunizations as are recommended or mandated by the Commissioner, as the case may be, including post-exposure prophylactic doses, in

the event that the Commissioner [, or his or her designee,] declares that an outbreak of a communicable disease exists or is threatened for which an immunization or program of immunizations is available.

(c) Carriers shall provide benefits or services for immunizations to be the same extent as for other medical conditions under the health benefits plan, except that no carrier shall require satisfaction of any deductible, in whole or in part, prior to the provision of benefits or services for immunizations to covered children.

1. A carrier may require payment of a co-payment to the extent that the co-payment shall not exceed the co-payment for other similar services, except that no co-payment shall apply to a Medicaid enrolled child participating in either Plan A, Plan B, Plan C, or Plan D of the New Jersey Medicaid or [New Jersey KidCare] NJ FamilyCare Programs.

(d) Carriers shall not deny benefits or services for immunizations provided to a covered child at an age that is later than that set forth in the "2007 Recommended Childhood and Adolescent Immunization Schedule," and as described in the ACIP Recommendations, as set forth at N.J.A.C. 8:57-8.2, if the immunization is otherwise necessary to complete the schedule of immunizations for that child as specified in the 2007 Recommended Childhood and Adolescent Immunization Schedule[.], and as described in the ACIP Recommendations.

(e) (No change.)

8:57- [8.4] 8.5 Penalties

(a)-(b) (No change.)

[N.J.A.C. 8:57-3] CHAPTER 58

REPORTABLE OCCUPATIONAL AND ENVIRONMENTAL DISEASES, INJURIES, AND [POISONS] POISONINGS

SUBCHAPTER 1. OCCUPATIONAL AND ENVIRONMENTAL DISEASES, INJURIES, AND POISONINGS

8:58-1.1 Purpose and scope

(a) This chapter contains rules intended to:

1. Provide a framework for reporting occupational and environmental disease, injury and poisoning;

2. Enable the Department to conduct surveillance and research activities; and

3. Prevent occupational and environmental disease, injury, and poisoning through early detection, exposure reduction, and elimination of hazards.

(b) This chapter applies to each hospital and health care provider licensed in New Jersey and establishes procedures concerning the reporting of occupational and environmental disease, injury, and poisoning.

8:58-1.2 Incorporated documents

(a) The Department incorporates by reference the following form in this chapter:

1. Occupational and Environmental Disease, Injury, or Poisoning Report by Health Care Provider (OCC-31) (Appendix) is the form required of a health care provider in order to report an occupational or environmental disease, injury, or poisoning to the Department.

2. The OCC-31 is available:

i. By written request to:

New Jersey Department of Health and Senior Services,

Occupational Health Service

PO Box 360

Trenton, NJ 08625-0360; or

ii. Online through the Occupational Health Service web page at http://nj.gov/health/eoh/survweb/ or the Department's Forms web page at http://web.doh.state.nj.us/forms.

8:58-1.3 Definitions

The following words and terms, as used in this chapter, shall have the following meanings, unless the context clearly indicates otherwise:

"Administrator" means the chief administrator or other person having control or supervision over any hospital.

"Commissioner" means the Commissioner of the New Jersey Department of Health and Senior Services, or his or her designee.

"Confirmed work-related asthma" means diagnosis of asthma and objective evidence of work-relatedness.

"Department" means the New Jersey Department of Health and Senior Services.

"Discharge summary" means a computerized record containing information compiled by hospitals on each patient's stay, such as codes for the most relevant diagnosis and secondary diagnoses, any procedures performed on the patient, and the admission and discharge dates of the patient's episode of care.

"Health care provider" means a person who is directly involved in the provision of health care services, such as the clinical diagnosis of disease and the prescribing of medications, and when required by State law, the individual has received professional training in the provision of such services and is licensed or certified for such provision.

1. This definition includes physicians, physician assistants, nurse practitioners, and clinical nurse specialists.

"Hospital" means an institution, whether operated for profit or not, which maintains and operates facilities for the diagnosis, treatment, or care of two or more non-related individuals suffering from illness or injury and where emergency, outpatient, surgical, obstetrical, convalescent, or other medical and nursing care is rendered for periods exceeding 24 hours.

"Hospital discharge data" means a set of computerized records that hospitals create at the time of patient discharge, which contain information that hospitals retrieve from patients' medical charts in accordance with N.J.S.A. 26:2H-1 et seq. and N.J.A.C. 8:31B-2.

"Possible work-related asthma" means symptoms of asthma and patient-reported work-related temporal pattern of symptoms of asthma.

"Probable work-related asthma" means diagnosis of asthma and patient-reported work-related temporal pattern of symptoms of asthma.

[8:57-3.1] 8:58-1.4 Hospital [Reporting] reporting of occupational and environmental diseases, injuries, and poisonings [by hospitals]

(a) [The chief administrator or other persons having control or supervision over any hospital in which any person has been diagnosed with any of the diseases or poisonings listed in (b) and (c) below shall report such disease or poisoning to the Department. The routine mechanism for reporting shall be electronic hospital discharge data reported to the Department under N.J.S.A. 26:2H-1 et seq. and N.J.A.C. 8:31B-2. At the discretion of the Department, the Department may require paper reporting of one or more of the listed reportable diagnoses within 30 days following written notification to hospitals. The disease or poisoning shall be considered diagnosed if it is listed as a primary or secondary diagnosis on the discharge summary.] The administrator of any hospital in which any person has been diagnosed with any of the diseases, injuries, or poisonings

listed in subsections (b) and (c) below shall report such disease or poisoning to the Department.

1. The administrator shall consider a disease, injury, or poisoning diagnosed, if the disease, injury, or poisoning is listed as a primary or secondary diagnosis on the discharge summary.

(b) The administrator shall report the following diseases [are declared to be reportable to the parties specified in (a) above] to the Department for purposes of this section using the codes established in the International Classification of Diseases Ninth Revision (ICD-9) (a), published by the World Health Organization, available for download at the National Center for Health Statistics' webpage http://www.cdc.gov/nchs/about/major/dvs/icd9des.htm., in the manner prescribed by subsection (d) below: [All diseases listed herein coded according to the 9th ICD revision are to be reported in the manner prescribed by (d) below:]

1.-9. (No change.)

(c) The administrator shall report poisoning due to the following and not the result of a suicidal attempt [shall also be reported to the parties specified in (a) above] to the Department in the manner prescribed by subsection (d) below:

1. [alcohol] Alcohol (excluding alcoholic beverages and alcoholism)	ICD 980; E860.1-.9
2. [petroleum] Petroleum products	ICD 981; E862 (E862.0-.9)

3. [solvents] Solvents other than petroleum based	ICD 982 (982.0-.9); E862 (E862.0-.9)
4. [corrosive] Corrosive aromatics and caustic alkalis	ICD 983 (983.0-.9); E864 (864.0-.4)
5. [lead] Lead and its compounds	ICD 984; E866 (E866.0)
6. [other] Other metals	ICD 985 (985.0-.9); E866 (E866.1-4)
7. [carbon] Carbon monoxide	ICD 986; E867, E868 (E868.0-.9)
8. [other] Other gases, fumes, or vapors	ICD 987 (987.0-.9); E869 (E869.0-.9)
9. [other] Other substances	ICD 989 (989.0-.9) E861 (E861.0-.9), E863 (E863.0-.9) E866 (E866.0-.9)

(d) [When requested by the Department in writing, the report required by (a) above shall state, on forms supplied by the Department, the name and current ICD code of the disease or poisoning and shall indicate whether this condition was a primary or secondary diagnosis. The following information on the person diagnosed with such disease or poisoning shall also be furnished: name, home address, telephone number, medical record number, date of birth, sex, race, name, address and telephone number of employer. The report shall also include the name of the attending physician, the reporting hospital, the date of discharge and such other information as may be required by the Department.] The routine

mechanism for hospital reporting shall be electronic hospital discharge data reported to the Department under N.J.S.A. 26:2H-1 et seq. and N.J.A.C. 8:31B-2.

(e) The Department may require hospitals to provide additional information after receipt of a specific report if information is missing or other information is necessary to carry out its public health mandate in accordance with the purpose of this chapter.

[8:57-3.2] 8:58-1.5 Health care provider [Reporting] reporting of occupational and environmental diseases, injuries, and poisonings [by physicians and advanced practice nurses]

(a) The [physician] health care provider attending any person who is ill or diagnosed with any of the diseases [or], injuries, or poisonings listed in subsection (b) below shall, within 30 days after [such condition has been diagnosed or treated] diagnosis or treatment, report such condition to the Department [of Health and Senior Services].

1. The health care provider may delegate these reporting activities to a member of the staff, but this delegation does not relieve the health care provider of the ultimate reporting responsibility.

(b) The health care provider shall report the following diseases, [and] injuries, and poisonings [are declared to be reportable] to the Department [of Health and Senior Services] for purposes of this section in the manner prescribed

by subsection (c) below[.]: [All conditions listed herein are to be reported in the manner prescribed by (c) below:]

1.-3. (No change.)

4. [Occupational] Work-related asthma: possible, probable, and confirmed;

5.-13. (No change)

14. Work- related [Carpal] carpal tunnel syndrome; [and]

15. Poisoning caused by known or suspected occupational exposure[.]; and

16. Other occupational disease.

(c) The health care provider shall report the information required pursuant to subsection (a) above using the Occupational and Environmental Disease, Injury, or Poisoning Report by Health Care Provider form (OCC-31), available in the Appendix. [report required by (a) above shall state the name of the disease, injury, or poisoning and the name of the reporting physician or advanced practice nurse. The following information on the person ill or diagnosed with such condition shall also be furnished: name, date of birth, sex, home address, telephone number, name, address, and telephone number of employer at the time of exposure or injury, and the date of onset of the disease, injury or poisoning. Additional information may be required by the Department after receipt of a specific report.]

(d) The Department may require a health care provider to submit additional information after receipt of a specific report if information is missing or other information is necessary to carry out its public health mandate in accordance with the purpose of this chapter.

[8:57-3.3] 8:58-1.6 Confidentiality

(a) [The reports made pursuant to this subchapter shall be used only by the Department, and such other agencies as may be designated by the Commissioner to carry out mandated duties, including the duty to control and suppress occupational and environmental diseases, injuries and poisonings.] The reports and forms submitted to the Department pursuant to this chapter contain demographic and medical information related to the Department's investigations and epidemiological studies of occupational and environmental diseases, injuries, and poisonings and shall not be considered "government records" subject to public access or inspection within the meaning of N.J.S.A. 47:1A-1 et seq. and shall be deemed:

1. "Information relating to medical . . . history, diagnosis, treatment, or evaluation" within the meaning of Executive Order 26, §4(b)1 (McGreevey, August 13, 2002); and/or

2. "Records concerning morbidity, mortality and reportable diseases of named persons required to be made, maintained or kept by any State or local

governmental agency" within the meaning of Executive Order 9, §2(c) (Hughes, September 30, 1963); and/or

3. Information "for use in the field of forensic pathology or for use in medical or scientific education or research" pursuant to N.J.S.A. 47:1A-1.1.

(b) [Medical and epidemiologic information which is gathered in connection with an investigation of a reportable disease, injury or poisoning and which identifies an individual is confidential and not open to public inspection without the individual's consent, except as may be necessary to carry out duties to protect the public health as determined by the Department.] The Department, and such other agencies as the Commissioner may designate, shall use the reports submitted pursuant to this chapter to carry out mandated duties, including the duty to control and suppress occupational and environmental diseases, injuries, and poisonings.

(c) [Medical and epidemiologic information collected pursuant to this subchapter may be disclosed in statistical or other form which does not disclose the identity of any individual.] Medical and epidemiologic information which the Department gathers in connection with an investigation of a reportable disease, injury or poisoning and which identifies an individual is confidential and not open to public inspection without the individual's consent, except as may be necessary to carry out the Department's duties to protect the public health.

(d) The Department may disclose medical and epidemiologic information collected pursuant to this chapter in statistical or other form, which does not disclose the identity of any individual.

8:58-1.7 Penalties

(a)Any hospital administrator or health care provider that violates any provision of this chapter shall be subject to the penalties established at N.J.S.A. 26:1A-10.

1. Each violation of any provision of this chapter shall constitute a separate offense.

8:36-18.4 Employee health and resident policies and procedures for infection prevention and control

(a)-(k) (No change.)

(l) The facility shall maintain records documenting contagious diseases contracted by employees during employment, as specified at N.J.A.C. 8:57-[1.3(a) and (b)] 1.5.

8:39-27.4 Mandatory post mortem policies and procedures

(a)-(d) (No change.)

(e) The body of a deceased resident who, at the time of death, had a communicable disease as defined in N.J.A.C. 8:57-[1.2] 1.3 shall be tagged accordingly before being released from the facility.

(f) (No change.)

8:43D-15.4 Employee health and resident policies and procedures for infection prevention and control

(a)-(l) (No change.)

(m) The facility shall maintain records documenting contagious diseases contracted by employees during employment, as specified at N.J.A.C. 8:57-[1.3(a) and (b)] 1.5.

(n) (No change.)

8:43H-20.2 Infection control policies and procedures

(a) (No change.)

(b) The infection control professional that is responsible for the infection control program shall implement the following mandatory requirements, but may implement additional infection control methods, as deemed necessary and appropriate by the facility:

1.-6. (No change.)

7. Identification and reporting of HIV/AIDS existing throughout the hospital, as specified in N.J.A.C. 8:57-[2.7] 2.11, Reporting of acquired immunodeficiency syndrome and infection with human immunodeficiency virus.

(c)-(g) (No change.)

8:52-12.3 Surveillance

(a)-(c) (No change.)

(d) Each local health agency shall ensure that there is a mechanism to receive reports and to respond to immediately reportable communicable diseases and conditions in accordance with N.J.A.C. 8:57-[1.3] 1.5. This mechanism shall be capable of operating 24 hours per day, seven days per week, including weekends and holidays.