HEALTH

PUBLIC HEALTH SERVICES BRANCH

Reportable Communicable Diseases, Infections, and Conditions; Reportable Zoonotic Diseases Occurring in Animals; Communicable Disease Reporting and Surveillance System; New Jersey Immunization Information System; Childhood Immunization; and Immunization of Collegians

Collection, Processing, Storage and Distribution of Blood

New Jersey Youth Camp Safety Standards

Tanning Facilities

Standards for Licensure of Assisted Living Residences, Comprehensive Personal Care Homes, and Assisted Living Programs

Standards for Licensure of Long-Term Care Facilities

Manual of Standards for Licensing of Ambulatory Care Facilities

Standards for Licensure of Pediatric Community Transitional Homes

Hospital Licensing Standards

Public Health Practice Standards of Performance for Local Boards of Health In New Jersey

Proposed New Rules: N.J.A.C. 8:57-1.4, 1.6, 1.8, 2.1, 2.5, 2.12, 2.13, 3.17, 3.18, 4.3, 4.6, 6.17, and 6.18, and Appendices A, D, F, G, K, L, P, T, U, V, and X

Proposed Repeals: N.J.A.C. 8:57-1.12, 3.2, 3.3, 3.17, 3.18, 3.21, 3.23, 4.7, 4.8, 4.14 through 4.21, 4.23, 6.16, 6.18 through 6.21, and 8:57-3 Subchapter Appendices E and G

Proposed Repeals and New Rules: N.J.A.C. 8:57-1.1, 2.1, 4.5, 4.9, 4.10, 4.11, 4.12, 4.13, and 6.1 through 6.15

Proposed Recodifications with Amendments: N.J.A.C. 8:57-1.3 as 1.2, 1.4 as 2.2, 1.5 as 2.3, 1.6 as 2.4, 1.7 through 1.11 as 2.6 through 2.10, 1.13 as 2.11, 1.14 as 1.7, 1.15 as 1.4, 3.4 through 3.16 as 3.2 through 3.14, 3.19 as 3.15, 3.20 as 3.16. 3.22 as 3.17, 4.3 as 4.7, 4.4 as 4.8, 4.6 as 4.4, 4.22 as 4.14, 4.24 as 1.5, 6.17 as 6.16, Subchapter 1 Appendices A and B as Appendices S and R, Subchapter 3 Appendices A through F, H, I, and J as Appendices B, C, D, V, G, H, I, and J, Subchapter 4 Appendix as Appendix M, Subchapter 5 Appendices A and B as Appendices N and O, and Subchapter 6 Appendix as Appendix Q

Proposed Amendments: N.J.A.C. 8:8-5.2; 8:25-1.4 and 5.5; 8:28-1.2, 8:36-18.4; 8:39-19.4 and 27.4; 8:43A-14.2, 8:43D-15.4; 8:43G-14.1 and 19.15; 8:43H-20.2; 8:52-3.3, 12.3, and 14.1 and Chapter 52 Appendix; and 8:57-3.1, 4.1, 4.2, 5.1, 5.3 through 5.6, 5.8 through 5.12, 5.14, 5.16, and 6.2

Authorized By: Jeffrey A. Brown, Acting Commissioner, Department of Health, and in consultation with the Public Health Council.

Authority: N.J.S.A. 4:19-15.14 et seq.; 17:23A-13.1; 17:48-6i and 6m; 17:48A-7h; 17:48E-35.6 and 35.10; 17B:26-2.1h; 17B:27-46.1h and 46.1*l*; 17B:27A-7; 18A:40-20, 21.1, 21.2, 26, and 42; 18A:61D-1 et seq., specifically N.J.S.A. 18A:61D-6; 18A:62-15, 15.1 and 15.2; 18A:75A-1 et seq., specifically 18A:75A-4, 5, and 13; 24:15-10; 26:1A-1 et seq., specifically 1A-7, 9, 9.1, and 15; 26:2-137.1 and 137.7; 26:2F-3, 13, and 13.2; 26:2H-1 et seq., specifically 2H-5 and 26:2H-18.79; 26:2J-4.6 and 4.10; 26:2N-1 et seq., specifically 2N-2, 7.1, and 7.2; 26:2T-1 et seq., specifically 2T-4; 26:4-1

through 26:4-59; 26:4-60 through 72, specifically 26:4-70; 26:4-78 through 95; 26:4-96 through 26:4-100.13, specifically 26:4-100.3; 26:4-129 and 130; 26:4-131 through 138, specifically 134; 26:12-1 et seq., specifically 26:12-5 and 16; 26:13-1 et seq.; 30:5B-1 et seq., specifically 30:5B-5; 34:9A-12 and 13; 45:9-42 through 45:9-42.25, specifically 45:9-42.24; 45:9-42.26 through 42.49, specifically 45:9-42.34 and 42.35; and 47:1A-1 et seq.; and P.L. 2005, c. 222, § 35; Reorganization Plan No. 003-2005 (Governor Codey, June 27, 2005), 37 N.J.R. 2735(a) (August 1, 2005)

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

Proposal Number: PRN 2025- .

Submit written comments by , 2025, electronically to http://www.nj.gov/health/legal/ecomments.shtml, or by regular mail postmarked by , 2025, to:

Genevieve Raganelli, Regulatory Officer
Office of Legal and Regulatory Compliance
Office of the Commissioner
New Jersey Department of Health
PO Box 360
Trenton, NJ 08625-0360

The agency proposal follows:

Summary

N.J.A.C. 8:57 Communicable Diseases, establishes standards for the reporting, investigation, and other activities attendant to the identification of cases of, at

Subchapter 1, communicable diseases, infections, or conditions pursuant to N.J.S.A. 26:4-1 et seq., and reportable zoonotic diseases occurring in animals pursuant to N.J.S.A. 4:19-15.14 et seq., and 26:4-78 et seq., and, at Subchapter 5, tuberculosis pursuant to N.J.S.A. 26:4-70. The chapter establishes, at Subchapter 3, standards for an automated and electronic immunization registry, known as the "New Jersey Immunization Information System," pursuant to N.J.S.A. 26: 4-131 et seq., the "Statewide Immunization Registry Act." The chapter establishes standards addressing, at Subchapter 4, childhood immunization pursuant to N.J.S.A. 26:1A-7 and 26:2-137.1, and, at Subchapter 6, immunization of collegians entering and attending institutions of higher education pursuant to N.J.S.A. 18A:61D-1 et seq., and 18A:62-15.1 and 15.2.

Reorganization Plan No. 003-2005 (Governor Codey, June 27, 2005), 37 N.J.R. 2735(a) (August 1, 2005) ("Reorganization Plan") transferred the functions, powers, and duties of the Public Health Council, other than its advisory and consultative functions, to the Department of Health (Department), to be allocated within the Department by the Commissioner.

N.J.A.C. 8:57 was to expire on March 10, 2016. On February 8, 2016, the Department readopted the chapter without change, thereby extending the chapter expiration to February 8, 2023. 48 N.J.R. 420(a). On June 16, 2022, the Department recodified N.J.A.C. 8:57-2, Reporting of Acquired Immunodeficiency Syndrome (AIDS) and Infection with Human Immunodeficiency Virus (HIV), as new N.J.A.C. 8:65, HIV Infection Reporting, with amendments, repeals, and new rules. 53 N.J.R. 1440(a), 54 N.J.R. 1408(a).

In 2023, the Department undertook extensive efforts to obtain stakeholder feedback on this rule. The Department prepared and distributed a presentation identifying the more significant changes to the chapter that the Department was considering, and a survey. The survey asked for comments on all topics that the presentation addressed, or any other aspects of the existing rule. The Department distributed the presentation directly to 34 identified stakeholders, including State agencies, hospital associations, and local health professional associations and interest groups, among others. The Department also distributed the presentation through the New Jersey Local Information Network and Communications System (LINCS) to LINCS agencies (see N.J.S.A. 26:13-2), which include local health officers and public and private health organizations. The Department received over 650 responses to this survey commenting on all subchapters of N.J.A.C. 8:57 and capturing a variety of health concerns. The Department circulated the comments to appropriate program staff members, based on their respective areas of expertise and took these comments and staff feedback thereon into consideration in drafting proposed revisions to N.J.A.C. 8:57.

The expiration date of N.J.A.C. 8:57 was extended by Gubernatorial Order from February 8, 2023, to February 8, 2024. 55 N.J.R. 390(a).

On January 3, 2024, the Department readopted N.J.A.C. 8:57-1, 3, 4, 5, and 6, without change, thereby extending the chapter expiration date for those subchapters to January 3, 2031, and permitted Subchapter 8, Childhood Immunization Insurance Coverage, to expire on February 8, 2024. 56 N.J.R. 213(a).

On February 5, 2024, the Department proposed to readopt and recodify N.J.A.C. 8:57-7, Student Health Insurance Coverage, as new N.J.A.C. 8:92, Higher Education

Student Health Insurance Coverage, with amendments and a new rule, thereby extending the subchapter expiration date to August 6, 2024. 56 N.J.R. 174(a). On May 17, 2024, the Department adopted the proposal. 56 N.J.R. 1094(a).

As the Department provides a 60-day comment period for this notice of proposal, it is exempt from the rulemaking calendar requirement.

The Department proposes to rename the chapter, Communicable Diseases, Infections, and Conditions; Reportable Zoonotic Diseases Occurring in Animals; Communicable Disease Reporting and Surveillance System; New Jersey Immunization Information System; Childhood Immunization; and Immunization of Collegians.

The Department proposes non-substantive amendments throughout the chapter, to correct spelling and grammar, improve readability, delete descriptive text and add instead acronyms and cross-references to terms that statutes and/or other rules establish, correct formatting of scientific terms, correct or update communication information and internet website links, and eliminate redundancy. The Department is proposing amendments in other chapters of Title 8 to correct cross-references to N.J.A.C. 8:57 and the chapter name, and the name of the Department, specifically in N.J.A.C. 8:8, 8:25, 8:28, 8:36, 8:39, 8:43A, 8:43D, 8:43G, and 8:52. The Department proposes to amend N.J.A.C. 8:25, New Jersey Youth Camp Safety Standards, Subchapter 5, Health, at N.J.A.C. 8:25-5.5 Health records, to add a cross-reference to N.J.S.A. 26:12-16, which establishes the immunization exemption available to a youth camper on religious grounds.

Subchapter 1

Existing Subchapter 1, Reportable Communicable Diseases, establishes standards addressing reportable communicable diseases, infections, and conditions. The Department proposes to amend the subchapter heading to be "General Provisions." The Department proposes to repeal existing N.J.A.C. 8:57-1.1, Purpose and scope, and add a new rule at N.J.A.C. 8:57-1.1, Purpose, to rearticulate the purpose of the chapter as establishing standards (1) for reporting communicable diseases, infections, and conditions and reportable zoonotic diseases occurring in animals, (2) governing the Communicable Disease Reporting and Surveillance System known as CDRSS (3) governing the automated and electronic immunization registry known as the "New Jersey Immunization Information System," and (4) addressing immunizations upon which administrators are to condition admission of minors to schools and child care centers, and collegians to institutions of higher education.

The Department proposes to repeal existing N.J.A.C. 8:57-1.2, Incorporated documents. As described more fully below, proposed new N.J.A.C. 8:57-1.4 would serve the purpose of this section.

Existing N.J.A.C. 8:57-1.3, Definitions, establishes definitions of words and terms the chapter uses. The Department proposes to recodify existing N.J.A.C. 8:57-1.3, Definitions, as new 1.2, Definitions. The Department proposes amendments throughout the chapter to delete or repeal subchapter-specific sections containing definitions and consolidate these in this section. The Department proposes to amend the section to add definitions of the following terms, some of which are to be relocated from the subchapter-specific definitions proposed for deletion or repeal: "AAP Red Book,"

“academic degree,” “academic term,” “ACIP recommendations,” “Adult Immunization Recommendations,” “Advisory Committee on Immunization Practices” or “ACIP,” “animal rescue organization,” “billing vendor,” “biologic,” “bioterrorism,” “birthing facility,” “carbapenemase gene,” “carbapenemase-producing organism” or “CPO,” “case,” “Catch-up Schedule,” “Centers for Disease Control and Prevention” or “CDC,” “Child and Adolescent Immunization Recommendations,” “Class B1 or B2 referral,“ “collegian,” “Communicable Disease Reporting and Surveillance System” or “CDRSS,” “Communicable Disease Service” or “CDS,” “condition,” “contact,” “contraindication,” “cosmetic establishment,” “Council of State and Territorial Epidemiologists” or “CSTE,” “designated agent,” “Directory of Local Health Departments in New Jersey,” “Division of HIV, STD, and TB Services,” “Division of Local Public Health,” “DNA,” “drug establishment,” “EBC,” “electronic case reporting,” “electronic health record vendor” or “EHR vendor,” “endemic level,” “farm or migrant labor camp,” “field services,” “FDA Food Code,” “food employee,” “food establishment,” “full-time collegian,” “health benefits plan,” “Healthcare Effectiveness Data And Information Set®” or “HEDIS®,” “healthcare personnel,” “healthcare professional,” “Health History and Appraisal form,” “health information exchange” or “HIE” or “health information network” or “HIN,” “health information organization” or “HIO,” “HL7 Implementation Guide,” “hospital,” “immunization,” “index case,” “infection,” “institution,” “institution of higher education” or “IHE,” “insurer,” “invalid dose,” “line list,” “local health agency,” “Local Information Network and Communications System” or “LINCS,” “Logical Observation Identifiers Names and Codes” or “LOINC,” “manager,” “Maternal and Child Health Consortium” or “MCHC,” “minor,” “Morbidity and Mortality Weekly Report” or “MMWR,” “MRSA

laboratory identification event" or "MRSA LabID event," "newborn," "New Jersey Immunization Information System" or "NJIIS," "NJ ELR Implementation Guide," "NJIIS access level," "NJIIS Personal Immunization Record," "NJIIS site," "NJIIS site administrator," "NJIIS user," "NJIIS webpage," "NJ Medicaid Program," "Notifiable Condition List," "nucleic acid amplification test" or "NAAT," "nursing home" or "nursing facility," "Official State of New Jersey School Immunization Record," "pan-non-susceptible organism," "parent," "part-time collegian," "pharmacist," "point-of-care test" or "POC test," "polymerase chain reaction" or "PCR," "practice management vendor," "precaution," "PSAST," "Public Health and Environmental Laboratories" or "PHEL," "pupil," "rabies post-exposure prophylaxis administration" or "rabies PEP administration," "referral laboratory," "registrant," "religious-affiliated facility," "RNA," "SARS," "satellite emergency department," "serologic test," "site administrator," "SNOMED," "surveillance case definition," "suspected outbreak," "vaccine," "valid dose," "Vaccine-Preventable Disease Program" or "VPDP," "veterinary diagnostic laboratory," "veterinary diagnostic laboratory director," and "virtual private network" or "VPN.

The Department proposes to delete the definitions of the following terms, which the chapter would not use: "kennel," "local health department," "multidrug-resistant organisms" or "MDROs," "nosocomial infection," "overlap agent or toxin," "pet shop," "pound," "shelter," and "Vancomycin-intermediate *Staphylococcus aureus*" or "VISA."

The Department proposes additional amendments to the existing definition of the term, "administrator." The Department proposes to amend the definition to reflect that the term means the person who controls or supervises a State psychiatric hospital; a facility under the jurisdiction of the Departments of Children and Families (DCF),

Corrections (DOC), or Human Services (DHS); and/or a residential health care facility not located with, and operated by, a licensed health care facility, under the jurisdiction of the Department of Community Affairs (DCA).

P.L. 1995, c. 284 (approved December 15, 1995), codified at N.J.S.A. 52:17B-169 et seq., established the Juvenile Justice Commission in, but not of, the DLPS, and transferred to that Commission jurisdiction over juvenile correctional facilities and related custodial facilities, such as pretrial detention facilities and various transitional program facilities, which were formerly under the jurisdiction of the DOC. N.J.S.A. 52:17B-176. P.L. 2025, c. 35 (approved March 17, 2025) renamed the Juvenile Justice Commission as the Youth Justice Commission (YJC). The Department proposes to amend the definition of the term, "administrator," to add a facility under the YJC's jurisdiction, to reflect the reallocation of control over those facilities from the DOC to the YJC.

In a previous rulemaking, the Department established a definition of the term, "health care facility," to mean facilities that the Department licenses pursuant to N.J.S.A. 26:2H-1 et seq. 40 N.J.R. 1962(a), 41 N.J.R. 1419(a). This had the unintended effect of removing the existing applicability of the chapter to custodial and/or residential facilities under the DHS' jurisdiction that provide health-related services. Therefore, the Department proposes to amend the definition of the term, "administrator," to refer to facilities operating under the jurisdiction of the DHS, to reflect the longstanding applicability of the chapter to facilities that provide health-related services at State institutions; see N.J.S.A. 26:4-19.

The Department proposes to amend the definition of the term, “administrator,” to add a reference to a farm or migrant labor camp and thereby reflect the communicable disease reporting obligations of a person in charge of this type of facility pursuant N.J.S.A. 34:9A-12 and 13.

The Department proposes to amend the definition of the term, “administrator,” to add a reference to an insurer, as N.J.S.A. 17:23A-13.1 et seq., and 17B:17-1 et seq., use that term, to reflect the obligation that State law imposes on insurers, if they require applicants for insurance “to submit to medical testing as a condition of issuing, extending or renewing” that insurance, to “promptly provide the Department of Health … a copy of the results of the test,” if “in the course of the testing the insurer determines that the applicant has a reportable communicable disease.” N.J.S.A. 17:23A-13.1.

The Department proposes to delete the reference to a person in charge of a “preschool” from the definition of the term, “administrator,” because the chapter does not use the term, “preschool,” to refer to a separate type of facility, independent of its inclusion within the meaning of the defined term, “child care center,” as proposed for amendment.

The Department proposes to amend the existing definition of the term, “certified animal control officer” to define that term by reference to its statutory definition at N.J.S.A. 4:19-15.1.

The Department proposes to amend the existing definition of the term, “child care center,” to refer to the statutory definitions at N.J.S.A. 30:5B-1 et seq., specifically at 30:5B-3 and include an “early childhood program” as N.J.A.C. 3A:52-1.4, 6A:14-1.3,

and 10:122-1.3 define that term and a public or private preschool program as being within the meaning of the term.

The Department proposes technical amendments to the existing definitions of the terms, “Commissioner” and “Department” to reflect the renaming of the Department pursuant to N.J.S.A. 26:1A-2.1.

The Department proposes to amend the existing definition of the term “communicable disease” by reference to the statutory definition of that term.

The Department proposes to amend the existing definition of the term, “electronic laboratory reporting” or “ELR,” to mean laboratory test result reporting in accordance with the format specified in, at the option of the reporter, either the national HL7 or the Department’s implementation guide. The Department’s implementation guide is a lesser-included subset of the data fields that the HL7 implementation guide requires. This is to accommodate laboratories that engage in multistate reporting, which might require more data than that which the Department requires.

The Department proposes to amend the existing definition of the term, “influenza virus, novel strain” to be “influenza A virus, novel,” and correspond to the CSTE surveillance case definition of the term, “novel influenza A virus infection.”

The Department proposes to amend the existing definition of the term, “neonatal,” to mean occurring in a newborn.

The Department proposes to amend the definition of the term, “outbreak,” to delete internal definitions of terms that the chapter as proposed for amendment would separately define.

The Department proposes to amend the definition of the term “veterinarian” by reference to N.J.S.A. 45:16-1 et seq.

As discussed more fully below, the Department proposes to recodify, with amendments, existing N.J.A.C. 8:57-1.4 through 1.11, 1.13, and 1.15, to be part of proposed new Subchapter 2.

N.J.A.C. 8:57-1.3 is reserved.

N.J.A.C. 8:57-1.4 through 1.11, and 1.13, are proposed for recodification with amendment into proposed new Subchapter 2, as described below. The Department proposes to repeal existing N.J.A.C. 8:57-1.12, Medical examination and specimen submission.

The Department proposes to recodify existing N.J.A.C. 8:57-1.15, Enforcement, which addresses enforcement of the subchapter, as new N.J.A.C. 8:57-1.4, Enforcement, and amend the section to indicate that it applies to chapter-wide noncompliance, refer to applicable laws that authorize the imposition of fines and other sanctions including disciplinary and enforcement measures under the implementing jurisdiction of State and other credentialling bodies, and delete the reference to “physician,” and thereby reflect that the chapter also imposes reporting and other compliance obligations on additional entities, as indicated in proposed new N.J.A.C. 8:57-2.1, Scope. These include: an administrator, an animal facility manager, a certified animal control officer, a clinical laboratory director, an employer and/or other person in charge at a food establishment, drug establishment, and/or cosmetic establishment, a healthcare professional, a health officer, a veterinarian, and a veterinary diagnostic laboratory director. The Department proposes to delete paragraph (a)1, referring to the

Department's option to issue notice and warning prior to initiating enforcement activity, to delete existing subsections (b) through (f), which contain references to the specific credentialing or licensing bodies and their respective statutory authority over the various entities upon whom the chapter imposes requirements, and to add new subsection (b), which would list entities subject to the chapter as to which the Department has enforcement or regulatory jurisdiction and authority.

Existing N.J.A.C. 8:57-4.24, Penalties, identifies the availability of penalties for violations of Subchapter 4. The Department proposes to recodify existing N.J.A.C. 8:57-4.24 as new 1.5, State Sanitary Code, penalties, with amendments. Proposed new N.J.A.C. 8:57-1.5(a) would indicate that, pursuant to N.J.S.A. 26:1A-7, the chapter is part of the State Sanitary Code. The Department proposes to recodify the existing text of this section as new subsection (b), to amend the text to indicate that violations of any part of the chapter, and not only Subchapter 4, are subject to the penalties and sanctions available at N.J.S.A. 26:1A-10, and refer to the availability of sanctions and penalties for violations of N.J.S.A. 26:4-129 and 137, and other applicable laws.

N.J.A.C. 8:57-1.6 is reserved.

Existing N.J.A.C. 8:57-1.14, Confidentiality, addresses the confidentiality and authorized uses of records and information that the Department holds pursuant to existing Subchapter 1. The Department proposes to recodify existing N.J.A.C. 8:57-1.14 as new 1.7, Confidentiality, and proposes to amend existing subsection (a) to indicate that the protections therein apply to records and information that a local health agency holds, in addition to the Department, pursuant to the entirety of Chapter 57, and not only Subchapter 1, and that the Commissioner may designate other entities, in

addition to those carrying out mandated duties, to have access to these materials, in accordance with applicable law. The Department proposes to delete existing N.J.A.C. 8:57-1.14(b), which repeats the content of N.J.S.A. 26:13-3d.

The Department proposes new N.J.A.C. 8:57-1.7(b), which would identify the circumstances in which the Department may release personally identifiable information that it obtains pursuant to the chapter. These circumstances are for purposes of research, with written consent, to protect the health of individuals, to cooperate with a multijurisdictional public health investigation, and/or pursuant to the order of a court of competent jurisdiction.

The Department proposes new N.J.A.C. 8:57-1.7(c), which would exclude isolation and quarantine orders, material containing the health information of natural persons who participate in medical testing, treatment, vaccination, isolation, or quarantine pursuant to the chapter, and any correspondence, records, reports, and other material associated with medical testing, treatment, vaccination, isolation, or quarantine of natural persons, from the definition of a “government record” that is subject to public access and inspection within the meaning of N.J.S.A. 47:1A-1 et seq., and declare these materials to be exempt from disclosure pursuant to other executive orders and laws. The proposed amendment would be consistent with protections that the Emergency Health Powers Act, N.J.S.A. 26:13-1 et seq., affords this material upon the Governor’s declaration of a public health emergency pursuant to N.J.S.A. 26:13-3. See N.J.S.A. 26:13-14, 15, 17, and 26. The Department perceives no rationale to limit the protection afforded this kind of individual health information only to circumstances warranting gubernatorial action declaring the existence of a public health emergency.

The Department proposes to recodify existing N.J.A.C. 8:57-1.14(d) as new N.J.A.C. 8:57-1.7(d) with an amendment to make the provision applicable to information collected pursuant to the entirety of N.J.A.C. 8:57. The Department proposes new N.J.A.C. 8:57-1.7(e), which would authorize the Department or a local health agency to withhold a record that it holds pursuant to the chapter that is otherwise subject to public access, regardless of whether individual identifiers have been removed or redacted from a record, if the agency has actual knowledge, or reason to believe, that the remaining unredacted information could be used, alone or in combination with other publicly accessible information, to identify an individual who is the subject of the record or to link an individual to the information contained therein.

The Department proposes new N.J.A.C. 8:57-1.7(f), which would generally track the Emergency Health Powers Act at N.J.S.A. 26:13-17 in establishing the purposes for which certain entities could obtain access to isolation, quarantine, and other health information, absent the order of a court of competent jurisdiction finding the need to provide access to avert a clear danger to an individual's or the public health. The Department proposes new N.J.A.C. 8:57-1.7(g), which would establish that the exemptions from public disclosure at subsections (a) through (f) would not apply to reports and records relating to diseases in animals made pursuant to N.J.A.C. 8:57-2.7, unless the record could be used alone or in combination with other information to identify health or other information about an individual as to which the individual may have a reasonable expectation of privacy; and/or that the agency is required or authorized to protect from public access or disclosure.

The Department proposes new N.J.A.C. 8:57-1.7(h), which would establish the circumstances and conditions that would authorize the Department to release otherwise protected records to the employer of an individual who is the subject of the record and other entities, such as healthcare personnel, school health officials, and IHE institutional liaisons.

The Department proposes new N.J.A.C. 8:57-1.7(i), which would establish the conditions that the Commissioner must determine to exist that would authorize the Department to release otherwise protected records about an individual pursuant to proposed new N.J.A.C. 8:57-1.7(h).

N.J.S.A. 26:2-137.1 directs the Department to specify the vaccine-preventable disease immunization requirements upon which to condition admission to and attendance at child care centers and schools, guided by the ACIP recommendations. N.J.S.A. 18A:61D-1 likewise directs the Department to specify the immunization requirements applicable to IHE attendees. N.J.S.A. 26:1A-7, as modified by Reorganization Plan No. 003-2005, directs the Commissioner, in consultation with the Public Health Council, to establish rules within the State Sanitary Code, “as may be necessary properly to preserve and improve the public health in this State.” N.J.S.A. 17:48-6i and 6m, 17:48A-7h, 17:48E-35.6 and 35.10, 17B:26-2.1h, 17B:27-46.1h and 46.1*l*, 17B:27A-7 and 19, and 26:2J-4.6 establish coverage requirements for health promotion services applicable to various health benefits plan types, including Department-recommended adult and childhood immunizations. Pursuant to this authority, the Department proposes new N.J.A.C. 8:57-1.8, Department procedure for the establishment of vaccine-preventable disease immunization recommendations and

requirements, to indicate the procedure by which the Department may establish recommendations and requirements for vaccine-preventable disease immunizations.

New Subchapter 2

Existing Subchapter 2 is reserved. The Department proposes to establish new Subchapter 2, Reportable Communicable Diseases, Infections, and Conditions, and as stated above, proposes to recodify existing sections of N.J.A.C. 8:57-1 within new Subchapter 2.

N.J.S.A. 26:4-1 states that the term, "communicable disease," means "any infectious or contagious disease so declared or defined by law, or which has been or may hereafter be declared a 'communicable disease' by the [Department]. N.J.S.A. 26:4-2 states, in part, that "to prevent the spread of disease affecting humans, the Department … shall have power to [declare] what diseases are communicable [and] when any communicable disease has become epidemic[; require] the reporting of communicable diseases[; maintain] and enforce proper and sufficient quarantine, wherever deemed necessary[; and remove] any person infected with a communicable disease to a suitable place, if … necessary."

N.J.S.A. 26:4-15 provides, "Every physician shall … after [the physician's] diagnosis that a person is ill or infected with a communicable disease or other disease required by any law of this State, the State Sanitary Code, or ordinance, to be reported, report such diagnosis and such related information as may be required by the … Department." N.J.S.A. 26:4-19 requires persons in control of public and private institutions "in which any person ill or infected with any disease required by law or the

State Sanitary Code to be reported [to] report the fact … and such other information as may be required by regulation of the … Department."

N.J.S.A. 26:4-78 through 95 establish standards for reporting known and suspected cases of rabies in animals. When an animal is known or suspected of either having, or having been bitten by another animal that is known or suspected of having, rabies, N.J.S.A. 26:4-78 requires "the owner or person in charge of the animal or any person having knowledge thereof" to "notify the local board having jurisdiction of the place where the animal is located."

N.J.S.A. 45:9-42.34 and 35 establish the Department's obligation, in consultation with the Public Health Council, to establish standards governing clinical laboratory operation, and clinical laboratory reporting of laboratory test results, "for the protection of the public health," as part of the State Sanitary Code.

Proposed new Subchapter 2 would implement these Department mandates by declaring the communicable diseases, infections, conditions, and laboratory testing information that are reportable, identifying entities that have reporting obligations, and establishing the manner and processes by which entities that have reporting responsibilities are to report.

The Department proposes new N.J.A.C. 8:57-2.1, Scope, to establish that the subchapter would apply to administrators, healthcare professionals, clinical laboratory directors, veterinarians, certified animal control officers, animal facility managers, veterinary diagnostic laboratory directors, health officers, and employers, and other persons in charge, at food establishments, drug establishments, and cosmetic establishments.

Existing N.J.A.C. 8:57-1.4, Health care provider and administrator reporting of reportable communicable diseases, establishes the obligation of health care providers and administrators to report certain communicable diseases, infections, and conditions. The Department proposes to recodify this section as new N.J.A.C. 8:57-2.2, Healthcare professional and administrator reporting and compliance obligations with respect to reportable communicable diseases, infections, and conditions. The Department proposes to amend existing subsection (a) to cross-refer to the reporting procedures at proposed new N.J.A.C. 8:57-2.4 and the disease-specific reporting deadlines at proposed new N.J.A.C. 8:57-2.3. The Department proposes to add new N.J.A.C. 8:57-2.2(a)1, which would require reporting of suspected or confirmed cases of the types listed at N.J.A.C. 8:57-2.3(a); (a)2, which would require reporting of confirmed cases of the types listed at N.J.A.C. 8:57-2.3(b) and (c); (a)3, which would require reporting of positive POC tests for the organisms listed at N.J.A.C. 8:57-2.6; and (a)4, which would require reporting of a confirmed case of a disease, condition, or illness not listed at N.J.A.C. 8:57-2.3, if it is on the infectious Notifiable Condition List for the year in which the case is identified. The Department proposes to amend existing subsection (b) to indicate that, while the section does not require duplicate reporting of cases, each entity with a reporting obligation remains responsible to ensure the submission of required reports, regardless of any arrangement into which entities with mutual reporting obligations for a case might enter to allocate responsibility for ministerial acts associated with reporting. The Department proposes to delete existing subsection (c) because it would be redundant of the proposed amendment at subsection (b). Proposed new subsection (c) would require a healthcare professional and an

administrator to comply with control measures that the Department or a health officer issues in writing with respect to individual named cases.

Existing N.J.A.C. 8:57-1.5, Reportable communicable diseases, establishes the lists of reportable communicable diseases and applicable reporting deadlines. The Department proposes to recodify this section as proposed new N.J.A.C. 8:57-2.3, Reportable communicable diseases, infections, and conditions. Existing subsection (a) provides a list of diseases, infections, or conditions that are immediately reportable, regardless of whether the case is suspected or confirmed, followed in parentheses by the causative organism, and existing subsection (b) establishes a list of communicable diseases, infections, or conditions that must be reported within 24 hours of confirmation of the case.

Many diseases, infections, or conditions that existing subsection (a) identifies as immediately reportable no longer pose the same public health threat, requiring immediate notification and response, as they may have in the past, whether this be due to advances in the field or because these diseases, infections, and conditions have become more routinely and readily treatable. Additionally, most modern disease reporting is accomplished through electronic means. This type of reporting is near instantaneous. Because of this, the Department can receive these reports faster than it did using the historical methods, allowing a much quicker response. In view of these changed circumstances, the Department reassessed which suspected or confirmed cases must be reported immediately and which could await case confirmation and be reported with less urgency. Additionally, the Department is proposing to add novel conditions to these lists.

Existing N.J.A.C. 8:57-1.5(a), proposed for recodification as new 2.3(a), establishes the list of immediately reportable, suspected or confirmed cases of a communicable disease, infection, or condition, or an outbreak thereof, and an act of bioterrorism. The Department proposes to amend subsection (a) to: (1) add to the list of immediately reportable diseases the following: biological intoxications, novel coronavirus that causes severe acute respiratory syndrome, free-living amebic infection, melioidosis, mpox (formerly known as monkeypox), plague, poliomyelitis, and rubella; (2) delete brucellosis, pertussis, and tularemia, and SARS as a separate entry (as the latter would be encompassed within the proposed addition of novel coronavirus causing severe acute respiratory syndrome); (3) modify the existing immediate reportability of strains of influenza A virus to include novel and/or unsubtypeable forms of the virus; (4) identify additional types of foodborne intoxication and viral hemorrhagic fever; (5) modify hantavirus to delete the qualifier of pulmonary syndrome; and (6) relocate the reference to reporting of a suspected or confirmed outbreak or act of bioterrorism to proposed new subsection (f), while retaining the immediate reportability of such events in accordance with subsection (a) and simplifying the description by using the defined term "communicable disease, infection, or condition" and deleting redundant description.

Existing N.J.A.C. 8:57-1.5(b), proposed for recodification as new 2.3(b), establishes the list of cases that are reportable "within 24 hours of diagnosis." The Department proposes to amend subsection (b) to require reporting by the close of the next business day following the date on which a healthcare professional confirms a diagnosis or receives a positive laboratory or POC test result, or other confirmation of a diagnosis. This would establish a more objectively measurable and enforceable

standard than the existing phrase, “within 24 hours of diagnosis.” The Department proposes to amend the list of reportable cases in subsection (b) to: (1) add alpha-gal syndrome, anaplasmosis, bacterial tickborne disease, brucellosis, *Candida auris* infection or colonization, carbapenemase-producing organism infection or colonization, chikungunya virus, COVID-19 infection (SARS-CoV-2), invasive *Cronobacter* infection in minors up to one year old, dengue virus, eastern equine encephalitis, extrapulmonary nontuberculous *Mycobacterium* (NTM) infection, *Haemophilus ducreyi,* influenza, Jamestown Canyon virus, leptospirosis, pertussis, Powassan virus disease, rabies exposure and cases in which rabies PEP is administered, RSV-associated pediatric mortality, spotted fever group rickettsiosis, tularemia, West Nile virus, and Zika virus; (2) delete Rocky Mountain spotted fever (which would be addressed by the addition of spotted fever group rickettsiosis); (3) modify the description of arboviral disease to add examples of viral diseases in this category (Bourbon, Cache Valley fever, California serogroup, Heartland, Japanese encephalitis, La Crosse encephalitis, and St. Louis encephalitis) and relocate yellow fever to this group from its existing listing as a separate disease (accompanied, as described above, by the addition of the common arboviruses dengue, eastern equine encephalitis, Powassan, West Nile, and Zika); (4) modify the reportability of hepatitis B, in addition to newly diagnosed cases, to cases occurring in persons who while pregnant test positive for hepatitis B surface antigen or virus DNA, or hepatitis E antigen, regardless of prior diagnosis, cases that were originally diagnosed in a jurisdiction or geographic subdivision other than New Jersey, and cases occurring in minors of up to 36 months of age born to persons who had hepatitis B during pregnancy with, and/or the birth of, the minor; (5) modify the

reportability of hepatitis C, in addition to newly diagnosed cases, to cases occurring in persons who test positive for hepatitis C RNA and/or antigen while pregnant, regardless of prior diagnosis, cases that were originally diagnosed in a jurisdiction or geographic subdivision other than New Jersey, and cases occurring in minors of up to 36 months of age born to persons who had hepatitis C during pregnancy with, and/or the birth of, the minor; (6) limit the reportability of Streptococcal disease, invasive group B to cases in infants who are fewer than 90 days of age; (7) delete amoebiasis, neonatal Chlamydial conjunctivitis, Creutzfeldt-Jakob disease, diarrheal disease, post-diarrheal hemolytic uremic syndrome, lymphogranuloma venereum, and tuberculosis; (8) modify sexually transmitted chlamydial infection to be *Chlamydia trachomatis* and, with influenza and Lyme disease, to require only electronic case reporting of these conditions; (9) relocate congenital syphilis to appear within syphilis, all stages; and modify the reportability of animal bites to mean bite of a human, regardless of whether the bite is treated for rabies; and (10) modify the causative organism for trichinellosis to be *Trichinella* spp., modify the causative organism for varicella disease to be varicella-zoster virus, and modify vibriosis to be vibriosis non-cholerae and indicate *Vibrio* spp. as the causative organism.

The Department proposes to delete existing N.J.A.C. 8:57-1.5(c), which reiterates the existing obligation created by N.J.S.A. 26:13-4 that persons with reporting obligations are to report, “[a]ny illness or health condition that is a potential cause of a public health emergency,” and add this obligation at proposed new subsection (f) as immediately reportable in accordance with subsection (a).

Existing N.J.A.C. 8:57-1.5(d), proposed for recodification as new 2.3(c), establishes standards for reporting cases of hospital-onset MRSA and hospital patient MRSA surveillance statistics. The Department proposes to amend this subsection to delete the existing description of MRSA reporting requirements and add in place thereof reference to the existing obligation of a hospital administrator to report MRSA LabID events to the NHSN in accordance with existing N.J.A.C. 8:56, Health Care Facility Infection Reporting.

The Department proposes new N.J.A.C. 8:57-2.3(d), which would require reporting of cases of suspected or confirmed tuberculosis (*Mycobacterium tuberculosis*) in accordance with N.J.A.C. 8:57-5.

Existing N.J.A.C. 8:57-1.5(e), proposed for recodification as new 2.3(e), establishes HIV case reporting standards. The Department proposes to amend subsection (e) to update the cross-reference therein to the applicable HIV case reporting standards at N.J.A.C. 8:65, HIV Infection Reporting.

Proposed new N.J.A.C. 8:57-2.3(f), as described above, would restate the reportability of suspected and confirmed outbreaks, bioterror events, and cases that may be a source of a public health emergency, while retaining these as immediately reportable in accordance with subsection (a). The Department proposes corresponding deletions of references to these events as reportable from existing subsection (a) and existing N.J.A.C. 8:57-1.6(e).

Existing N.J.A.C. 8:57-1.6, Method of reporting and content of report, establishes the method of reporting and the content of a required report. The Department proposes to recodify this section as new N.J.A.C. 8:57-2.4, Method of reporting and content of

report. Existing subsection (a) establishes standards for reporting immediately reportable cases. The Department proposes to amend subsection (a) to cross-refer to the list of immediately reportable conditions at proposed new N.J.A.C. 8:57-2.3(a), restate and reorganize the subsection through subcodification, simplify the description of the reporting process, identify the entities, by jurisdiction, to whom reports are to be made based on case location, identify procedures for alternative entities to whom reports are to be made if the primary recipient is unavailable, and delete redundant and superfluous text.

Existing N.J.A.C. 8:57-1.6(b), proposed for recodification as new 2.4(b), establishes standards for reporting cases that are reportable "within 24 hours of diagnosis." The Department proposes to amend subsection (b) to delete reference to this reporting period, add in place thereof a cross-reference to the list of conditions that would be reportable "by the close of the next business day following the date on which the diagnosis is confirmed" pursuant to proposed new N.J.A.C. 8:57-2.3(b), restate and reorganize the subsection through subcodification, including the addition of new subsection (c) to refer to the directory of local health departments in New Jersey, simplify the description of the reporting processes, identify the jurisdictions of entities to whom reports are to be made based on case location and/or reported condition; and identify procedures for reporting to alternative entities if the primary recipient is unavailable.

Existing N.J.A.C. 8:57-1.6(c), proposed for recodification as new 2.4(d), identifies the minimum content of a report that the subchapter requires. The Department proposes to amend this subsection to delete the reference therein, and throughout the

chapter, to the subject of a report as being “ill or infected,” and add instead reference to the subject using the defined term, “case,” to include those who are suspected of being ill or infected, in addition to persons in whom infection is confirmed.

Existing N.J.A.C. 8:57-1.6(d), proposed for recodification as new 2.4(e), identifies the minimum content of an outbreak report. The Department proposes to amend the subsection to identify additional demographic, identifying, and clinical information to be reported about each case within an outbreak. The Department proposes to delete existing subsection N.J.A.C. 8:57-1.6(e), the content of which the Department proposes to add to the list of immediately reportable conditions at proposed new N.J.A.C. 8:57-2.3(a) and (f).

Proposed new N.J.A.C. 8:57-2.4(f) would require a hospital that maintains an internet-based mechanism by which the Department could obtain access to the hospital’s health records regarding a case or an outbreak to notify the Department as to the procedure by which it might submit an access request.

The Department proposes a new rule at N.J.A.C. 8:57-2.5, Clinical laboratory reporting procedures and obligations with respect to laboratory results; establishment of electronic interface for ELR. This section would establish standards by which a clinical laboratory is to report the results of laboratory tests for the presence of the reportable organisms listed at existing N.J.A.C. 8:57-1.7, as proposed for recodification as new N.J.A.C. 8:57-2.6 and, with respect to ELR, establish an electronic interface with the Department. The Department proposes corresponding amendments to delete potentially redundant or conflicting reporting procedures and obligations at existing

N.J.A.C. 8:57-1.6, as proposed for recodification as new N.J.A.C. 8:57-2.4, specifically at (a)1 through 3, (b), (d), and (e).

Proposed new N.J.A.C. 8:57-2.5(a) would establish that a clinical laboratory is to report by means of ELR or electronic reporting unless otherwise specified at new N.J.A.C. 8:57-2.6. Proposed new subsection (b) would require a clinical laboratory, in establishing an ELR interface with the Department, to adhere to the ELR On-Boarding Manual, Version 1.5 (May 6, 2019), at Appendix S.

Proposed new N.J.A.C. 8:57-2.5(c) would require a clinical laboratory reporting by means of ELR to use the LOINC and SNOMED terminology standards and, as a maximum standard, at proposed new (c)1, in accordance with the HL7 Implementation Guide, which the chapter incorporates by reference, as amended and supplemented, at proposed new N.J.A.C. 8:57-1.2(b). The LOINC is a coding vocabulary of terminology used to describe laboratory test results, specifically observations and findings, whereas the SNOMED is a coding vocabulary for medical terms. The HL7 Implementation Guide establishes specifications for reporting laboratory results to health agencies of the USA, including messaging content and dynamics related to the transmission of reportable laboratory result messages. Each USA jurisdiction that requires clinical laboratories to report laboratory results specifies the findings that are reportable and the minimum content of those reports. Some clinical laboratories that report to the Department are multijurisdictional reporters and may elect to report the plenary content of the HL7 Implementation Guide to ensure compliance with differences in ELR requirements among health authorities and jurisdictions. Others may participate in Federal incentive programs designed to encourage “meaningful use” of electronic health records. Federal

standards for these incentive programs may condition eligibility on a clinical laboratory being able to demonstrate reporting ability in accordance with the HL7 Implementation Guide. The Department accepts reports containing all the content that HL7 Implementation Guide requires but retains only those data elements that it needs. The Department's information needs with respect to the content of laboratory result reports are less than the plenary content that the HL7 Implementation Guide requires, and the content the Department requires can increase or decrease as the State's need for epidemiological data changes. For example, if cases of a particular disease start to occur in greater numbers than expected, suggesting an outbreak, the Department's epidemiologists temporarily may need laboratories to report additional demographic or disease progression data on specimens to facilitate investigation and inform appropriate response measures, until the outbreak subsides.

As an alternative, less burdensome, standard than reporting in compliance with the HL7 Implementation Guide, and to accommodate clinical laboratories that are not multijurisdictional reporters, or that customize their reports by jurisdiction, proposed new N.J.A.C. 8:57-2.5(c)2 would authorize a clinical laboratory to elect to report in accordance with the NJ ELR Implementation Guide, which is a subset of the content that the HL7 Implementation Guide requires. The Department proposes to make the NJ ELR Implementation Guide available online, to allow revision as the State's epidemiological data needs might change, as described above. However, the NJ ELR Implementation Guide's compliance requirements would never exceed those of the HL7 Implementation Guide.

Proposed new N.J.A.C. 8:57-2.5(d) would establish the continuing obligation of a clinical laboratory director to ensure the reporting and/or submission of, respectively, laboratory results as to which proposed new N.J.A.C. 8:57-2.6 would require reporting, and culture isolates as to which proposed new N.J.A.C. 8:57-2.6 would require submission.

Existing N.J.A.C. 8:57-1.7, Reporting of positive laboratory results denoting diseases, establishes a list of communicable disease-causing organisms, the presence of which in laboratory findings a clinical laboratory is to report, and the applicable reporting deadlines. The Department proposes to recodify this section as new N.J.A.C. 8:57-2.6, Reportable laboratory results for certain organisms; reporting procedures; submission of culture isolates and other test specimens, to indicate that laboratories report results indicative of the presence of organisms, and do not make diagnoses. See N.J.S.A. 45:9-42.34 at subsection e, which states that "[clinical laboratory] reports shall not be construed as constituting a diagnosis." The Department proposes to amend existing subsection (a) to require a clinical laboratory director to report laboratory results indicative of the presence of the listed communicable disease, illness, or condition-causing organisms, and identify the manner in which, the deadlines by which, and the jurisdictions to which, a clinical laboratory director is to report, depending on the organism and the case location. The Department proposes to amend this subsection to identify organisms requiring, at proposed new paragraph (a)1, immediate reporting by telephone notice to the Communicable Disease Service; at proposed new paragraph (a)2, immediate electronic reporting and telephone notice to the local health agency with case jurisdiction; at proposed new paragraph (a)3, immediate electronic reporting,

including by a clinical laboratory that ordinarily reports by means of ELR; at proposed new (a)4 and (a)5, by ELR or electronic reporting by the close of the next business day following the receipt of results; and at proposed new (a)6, in accordance with N.J.A.C. 8:65, HIV Infection Reporting.

Proposed new N.J.A.C. 8:57-2.6(a)1 would require immediate telephone reporting to the Communicable Disease Service if a culture were suspected to contain *Bacillus anthracis*, *Brucella* spp., *Burkholderia mallei*, *Burkholderia pseudomallei*, *Francisella tularensis*, and *Yersinia pestis.* At new N.J.A.C. 8:57-2.6(a)2, the Department proposes to require immediate electronic reporting and telephone notice to the local health officer with case jurisdiction upon obtaining a laboratory result that indicates, or is positive (and, if indicated, negative) for, the presence of the following organism or antibodies: *Acanthamoeba* spp., *Bacillus anthracis*, *Balamuthia mandrillaris*, *Burkholderia pseudomallei*, unsubtypeable or novel influenza A virus, *Naegleria fowleri*, rubeola virus upon identification by specified serologic tests, variola virus, viruses that cause viral hemorrhagic fever (with corresponding proposed deletion of the existing separate references to the viruses the term comprises, that is, Ebola, Lassa, and Marburg), and *Yersinia pestis*. The Department proposes to delete from this category of reportable results the existing references to *Bordetella pertussis,* foodborne intoxication, including, but not limited to, ciguatera, paralytic shellfish poisoning, scombroid, or mushroom poisoning; *Francisella tularensis*; *Haemophilus influenzae*; hepatitis A; and rubella virus.

Proposed new N.J.A.C. 8:57-2.6(a)3 would require immediate electronic reporting, even if the laboratory ordinarily reports by ELR, of results indicative of the

presence of (positive for) the following organisms, and, if specified, negative results: acid-fast bacilli, *Haemophilus influenzae* from particular specimen sites, hepatitis A virus from certain tests and the results of certain additional tests if performed on the same specimen collection that yields the hepatitis A result, positive and negative orthopoxvirus monkeypox, and rubella virus if identified by serology testing and the results of certain additional tests if performed on the same specimen collection that yields the positive serology result. The Department proposes to amend this list to delete reporting of antibiotic-resistant organisms by a hospital-based laboratory.

Proposed new N.J.A.C. 8:57-2.6(a)4 would require reporting of laboratory test results that are positive, and in certain cases, negative, for the presence of the listed organisms by the close of the next business day. The Department proposes to: (1) require reporting of positive results for the following organisms: Alpha-gal, *Anaplasma* spp., arbovirus, *Bordetella pertussis*, *Borrelia* spp., *Cronobacter* spp., invasive infection, in minors up to one year of age, *Cryptosporidium* spp., *Cyclospora* spp., eastern equine encephalitis, *Giardia lamblia*, *Haemophilus ducreyi*, Jamestown Canyon virus, *Listeria monocytogenes, Neisseria gonorrhoeae*, nontuberculous *Mycobacterium* (NTM), respiratory syncytial virus, *Staphylococcus aureus*, *Streptococcus agalactiae*, *pneumoniae*, and *pyogenes*, when isolated from cerebrospinal fluid, blood or a normally sterile site, *Trichinella* spp., Varicella-zoster virus, and *Yersinia* spp., (2) require reporting of positive and negative results for the following organisms: Babesia spp., non-culture *Brucella* spp., *Candida auris*, Carbapenemase-producing organism, chikungunya virus, *Chlamydia psittaci*, non-culture *Coxiella burnetii*, *Cronobacter* spp., invasive infection, in minors up to one year of age, *Cryptosporidium* spp., dengue virus,

Ehrlichia spp., *Escherichia coli*, non-culture *Francisella tularensis*, influenza virus, *Klebsiella granulomatis*, *Legionella* spp., *Leptospira* spp., *Plasmodium* spp., *Rickettsia* spp., *Salmonella* spp., *Salmonella enterica* serotype Typhi, SARS-CoV-2, *Shigella* spp., *Treponema pallidum*, *Vibrio* spp., West Nile virus, and Zika virus; (3) modify the reportability of hepatitis B, hepatitis C, and mumps upon obtaining certain serology results and add as reportable the results of certain other tests if performed on a specimen collection yielding results of reportable hepatitis B, hepatitis C, or mumps virus; and (4) modify the reportability of test types and results for *treponema pallidum*.

Proposed new N.J.A.C. 8:57-2.6(a)5 would require a laboratory to report by means of ELR or electronic reporting by the close of the business day next following the day on which it obtains a result that is positive for a communicable disease-causing organism not listed in proposed new N.J.A.C. 8:57-2.6(a)1 through 4, if the organism is a cause of an infectious condition that appears on the CDC infectious Notifiable Condition List applicable for the year in which the result is obtained.

Proposed new N.J.A.C. 8:57-2.6(a)6 would require laboratory reporting of HIV in accordance with N.J.A.C. 8:65, HIV Infection Reporting.

Proposed new N.J.A.C. 8:57-2.6(b) would specify the required minimum content of a laboratory report that N.J.A.C. 8:57-2.6(a) requires. Proposed new paragraph (b)7 would require a laboratory to provide the initial reportable laboratory test reports upon request.

The Department proposes to delete existing subsection N.J.A.C. 8:57-1.7(b) and recodify existing subsection N.J.A.C. 8:57-1.7(c) as new 2.6(b). The Department proposes to delete existing subsection N.J.A.C. 8:57-1.7(d). The Department proposes

to recodify existing subsection N.J.A.C. 8:57-1.7(e) as new 2.6(c) and proposes to amend the subsection to modify the types of culture isolates and specimens that clinical laboratory directors are required to submit to the PHEL. Additions to this list would include *Candida auris*; carbapenemase-producing organisms (CPO); chikungunya serology specimens; nontuberculous mycobacteria (NTM) excluding *Mycobacterium leprae* and *Mycobacterium gordonae*, when collected from sterile body sites, excluding lower respiratory specimens; influenza A virus, novel and/or unsubtypeable; influenza virus, severe and fatal pediatric; *Legionella* spp., pan-non susceptible organisms; severe and fatal pediatric respiratory syncytial virus; high-level vancomycin-resistant Staphylococcus aureus (VRSA) from any body site; *Vibrio* spp.; and all IgM-positive West Nile virus specimens. Proposed deletions from this list would include *Candida haemulonii* species complex (to be replaced with *Candida auris*) and multidrug-resistant organisms (MDROs) (to be replaced with pan non-susceptible organisms).

The Department proposes to recodify existing subsection N.J.A.C. 8:57-1.7(f) as new 2.6(d) and proposes to amend the subsection to delete a reference to tuberculosis reporting and require a laboratory director to submit any specimen or isolate, obtained from humans, food, or other sources, which is associated with an outbreak or public health investigation and for which the Department issues a written request.

The Department proposes to delete existing N.J.A.C. 8:57-1.7(g), which requires certain hospital-based clinical laboratories to submit data that the Department no longer needs, and existing subsection (h), as redundant.

The Department proposes new N.J.A.C. 8:57-2.6(e), which would require a clinical laboratory director to submit to PHEL certain respiratory specimens tested for influenza virus, depending on the time of year.

The Department proposes to recodify existing N.J.A.C. 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, which addresses the reporting of certain zoonotic diseases and disease outbreaks, as new N.J.A.C. 8:57-2.7, Reporting obligations and procedures applicable to a veterinarian, a certified animal control officer, an animal facility manager, and a veterinary diagnostic laboratory.

Existing subsection (a) establishes the list of reportable zoonotic diseases, infections, and conditions and shows, in parentheses following each, the disease-causing organism. The Department proposes to amend this subsection to add a cross-reference to the case reporting procedure at proposed new N.J.A.C. 8:57-2.7(e) and add, to the list of reportable diseases in animals, canine brucellosis (*Brucella canis*), glanders (*Burkholderia mallei*), harmful algal bloom toxicity, melioidosis (*Burkholderia psuedomallei*), SARS-CoV-2, and tuberculosis.

Existing Subsection (b) provides a cross-reference to the existing obligation to report confirmed and suspected cases of rabies in any animal in accordance with the reporting procedure at N.J.A.C. 8:23-1.2. The Department proposes to amend existing subsection (c) to indicate that the subsection establishes the obligation to report confirmed and suspected outbreaks of any disease in domestic companion animals in accordance with the procedures at proposed new subsections (e) and (f).

The Department proposes to amend existing subsection (d) to track more closely the statutory obligation at N.J.S.A. 26:4-81 to report cases of persons being bitten by animals or exposed to rabies to the appropriate health officer with jurisdiction, to refer to the applicability of this reporting obligation to an animal rescue organization manager, and to add new paragraph (d)1 to reflect the statute's exemption from the reporting obligation when a person is treated by a healthcare professional.

The Department proposes new subsection (e), to indicate the manner by which one is to make the report that subsections (a) and (c) require, and to require the report to be submitted "by the close of the business day next following" the diagnosis or the outbreak identification by submission of either a completed Zoonotic Disease Incident Report form at proposed new Appendix A (CDS-32), or a written report containing the information the form requires.

The Department proposes to amend existing subsection (f) to use the defined term, "animal facility manager," and provide a cross-reference to the obligation of an animal facility to establish a program of disease control and health care under the supervision of a veterinarian at N.J.A.C. 8:23A-1.9.

The Department proposes to amend existing subsection (g) to indicate that, while duplicate reporting of the same case is unnecessary, entities having mutual reporting obligations with respect to a case remain obliged to ensure that the case is reported in accordance with the subchapter, regardless of any agreement to delegate ministerial tasks associated with reporting.

The Department proposes to amend existing subsection (h) to refer to a suspected or confirmed reportable zoonotic disease and outbreak of any disease

affecting animals under the jurisdiction of the Departments of either Agriculture or Environmental Protection.

The Department proposes to add new subsection (i), which would establish a list of organisms to be reported by a veterinary laboratory director to the Department within one business day following test completion, when identified in a domestic companion animal.

The Department proposes new subsection (j), which would identify procedures for reporting laboratory results pursuant to subsection (i).

The Department proposes to recodify existing N.J.A.C. 8:57-1.9, Reporting of diseases by health officers, which establishes the reporting obligations and procedures by which health officers are to report to the Department, and addresses jurisdictional issues, as new N.J.A.C. 8:57-2.8, Health officer reporting obligations and procedures. The Department proposes to amend existing subsection (a), which establishes the procedure by which health officers are to report immediately reportable cases and laboratory findings to the Department. The proposed amendment would require immediate telephonic and electronic reporting to the Department, upon a health officer's receipt of a report pursuant to N.J.A.C. 8:57-2.3(a), except telephone notice is not required for the following: *Haemophilus influenzae*, hepatitis A, mpox, and rubella. Proposed new subsection (b) would require a health officer receiving a report pursuant to N.J.A.C. 8:57-2.3(b) to report the case by electronic reporting by the close of the next business day. Proposed new subsection (c) would require a health officer receiving a report pursuant to N.J.A.C. 8:57-2.3(f) to immediately notify the Department by telephone. Proposed new subsection (d) would require a health officer receiving a

report of a laboratory result that is reportable pursuant to N.J.A.C. 8:57-2.6(a)2 to immediately notify the Department by telephone and, if the reporting laboratory has not already done so, by electronic reporting. The Department proposes to recodify existing subsection (b) as new subsection (e) and amend the subsection to require a health officer receiving a report of a laboratory result that is reportable pursuant to N.J.A.C. 8:57-2.6(a)3 to report the result by electronic reporting within 12 hours of receipt, if the reporting laboratory has not already reported the result. Proposed new subsection (f) would require a health officer receiving a report of a laboratory result that is reportable pursuant to N.J.A.C. 8:57-2.6(a)4 to report the result by electronic reporting by the close of the next business day, if the reporting laboratory has not already reported the result. Proposed new subsection (g) would require a health officer receiving a Zoonotic Disease Incident Report (or the content therein requested) to submit the report to the CDS by telefacsimile or electronic mail by the close of the next business day.

The Department proposes to recodify, as new subsection (h), existing (b)1, which establishes the obligation of a health officer to investigate an incomplete report and submit additional information to the Department. The Department proposes to recodify, as new subsection (i), existing (b)2, which establishes a procedure by which health officers experiencing circumstances that impede electronic reporting to fulfill their reporting obligations by other means. A proposed amendment would delete reference to mail reporting and establish that the Department would instruct a health officer as to an acceptable alternative means of reporting, which would depend on the nature of the case and the urgency of response.

Existing subsection (c) addresses health officer communications with respect to reports implicating multiple jurisdictions. The Department proposes amendments to reorganize the subsection as new subsections (j), (k), and (l). Proposed new subsections (j) and (k) would require a health officer to notify the health officer of another jurisdiction in which a case of a suspected or confirmed reportable communicable disease, infection, or condition, respectively, is known or believed to have been contracted, or resides. Proposed new subsection (*l*) would require a health officer to notify the Department when subsections (j) or (k) would require issuance of a notice to a jurisdiction outside of New Jersey. The Department proposes to delete existing subsection (d) because it unnecessarily reiterates the reporting responsibility of health officers who delegate ministerial functions associated with reporting.

The Department proposes to recodify existing N.J.A.C. 8:57-1.10, Health officer investigations, which establishes standards for health officer investigations of communicable diseases and outbreaks, as new N.J.A.C. 8:57-2.9, Health officer investigations. The Department proposes to amend subsection (a) to delete a reference to a guidance publication and indicate that a health officer is to investigate, in accordance with the section and the "Guidance for Prioritizing Communicable Disease Investigations," at Appendix T, each suspected and confirmed case of, at new paragraph (a)1, a reportable disease, infection, and condition, and at new paragraph (a)2, an outbreak of any disease, infection, or condition. The Department proposes to delete existing subsection (b).

The Department proposes to recodify existing subsection (c) as new (b) and amend the subsection to restate the actions that a health officer is to undertake in

performing an investigation. Proposed new paragraph (b)2 would add the obligation to determine the number of cases. The Department proposes to recodify existing paragraph (c)2 as new (b)3, delete therefrom the term, “spread,” and add in its place the phrase, “mode of transmission.” The Department proposes to recodify existing paragraph (c)3 as new (b)4. Proposed new paragraph (b)5 would require a health officer to collaborate with the Department on public health notifications including press releases and communications with constituents. Proposed new paragraph (b)6 would restate the existing obligation of a health officer to adhere to Department direction that the Department may issue under the circumstances of a case or outbreak.

The Department proposes to delete existing subsection (d), which is redundant of the reporting procedures at existing N.J.A.C. 8:57-1.9, as proposed for recodification with amendment as new N.J.A.C. 8:57-2.8. The Department proposes to recodify existing subsection (e), which addresses the factors implicating overlapping health officer jurisdiction with respect to an investigation, as new subsection (c), and amend the subsection to indicate that a jurisdiction is implicated in an investigation if the case or outbreak is suspected or confirmed to have been transmitted there, if the case is employed, maintains an additional residence, conducts other activities, or is receiving care there, or if the Department determines the jurisdiction to have a geographic nexus to the investigation.

The Department proposes to recodify existing subsection (f), which addresses multijurisdictional case coordination, as new subsection (d), and proposes to amend the subsection to use the defined term, “local health agency” rather than “local health

department," and indicate that other State and Federal entities may be involved in an investigation.

Proposed new subsection (e) would indicate that, pursuant to N.J.S.A. 26:1A-7, 26:4-2, 26:4-4, and A-9, each health officer is to conduct communicable disease investigations within the health officer's respective jurisdiction, including at a State-owned or affiliated building or facility. The Department proposes to recodify existing subsection (g) as new (f) and amend the subsection to require a health officer to report to the Department at least every 30 days on the status of each investigation in progress until the completion thereof, and more frequently, depending on specified factors. This would ensure that the Department remains apprised of the status of ongoing investigations, rather than having to wait until an investigation is "completed," and would encourage the prompt completion, when possible, of an investigation that might otherwise languish due to inactivity. The Department proposes to reorganize existing (g), which establishes the required content of a status report, as new subsections (f) and (g) and amend subsection (g) to add, to the minimum content of a required monthly status report, case counts, line lists, and, upon Department request, inspection reports and preliminary findings associated with site visits to locations associated with the investigation.

The Department proposes to delete existing subsection (h), which cross-refers to procedures for handling infected pet birds at N.J.A.C. 8:23-1.4, and subsection (i), which cross-refers to the Commissioner's powers pursuant to the Emergency Health Powers Act. Proposed new subsection (h) would identify disease-specific worksheets

that the Department makes available on its forms page for optional use by health officers in conducting investigations.

The Department proposes to recodify existing N.J.A.C. 8:57-1.11, Isolation and quarantine for communicable disease, which addresses isolation and quarantine for communicable disease, as new 8:57-2.10, Isolation and quarantine for communicable disease, infection, or condition. The Department proposes to amend subsection (a) to indicate that isolation and quarantine measures might be appropriate and would be available for both a suspected or confirmed case of a communicable disease, infection, or condition and add cross-references to N.J.S.A. 26:4 and 26:13.

The Department proposes to recodify existing Appendix B, the Model Rules for Local Boards of Health, as new Appendix R, the Model Ordinance for Quarantine and Isolation ("model ordinance"), with amendments. Proposed new N.J.A.C. 8:57-2.10(a)1 would state that a geographic subdivision of the State, such as a municipality or a county ("health jurisdiction"), might elect to enact the model ordinance. A health jurisdiction's adoption of the model ordinance, or a version thereof customized to local needs, would enable it to establish the preneed isolation and quarantine measures that it would use to prevent or control the spread of a quarantinable disease, infection, or condition, should a case or an outbreak occur within its jurisdiction. The Department proposes to amend the model ordinance to modify the definition of the term, "quarantinable disease," as used therein, to indicate that the term is not limited to communicable diseases, infections, and conditions that N.J.A.C. 8:57 identifies as reportable. This would facilitate the ability of a health jurisdiction to implement an appropriate public health response to emerging and novel diseases. The Department

proposes nonsubstantial and technical amendments throughout the model ordinance to ensure that it remains consistent with other proposed changes to N.J.A.C. 8:57, correct grammar, and improve readability.

Proposed new N.J.A.C. 8:57-2.10(a)2 would state that, with the Department's consent, an order issued pursuant to the section would remain in force unless terminated. The Department proposes to recodify existing N.J.A.C. 8:57-2.10(a)1 as new (a)3, with an amendment to use the defined term, "case." The Department proposes to delete existing (a)2 and 3. The Department proposes to amend existing subsection (b) to indicate that the subsection would apply to a quarantined case.

The Department proposes to delete existing subsection (c) and recodify existing subsection (d) as new subsection (c). The Department proposes to add new subsection (d), which would cross-refer to procedures for quarantine and other handling measures with respect to infected pet birds at N.J.A.C. 8:23-1.4. The Department proposes to add new subsection (e) to establish procedures for quarantining domestic companion animals if infected or exposed to reportable diseases set forth in N.J.A.C. 8:57-2.7 and proposes a corresponding amendment to delete as redundant a comparable provision at existing N.J.A.C. 8:57-1.10(h).

The Department proposes to repeal existing N.J.A.C. 8:57-1.12, Medical examination and specimen submission.

The Department proposes to recodify existing N.J.A.C. 8:57-1.13, Foodhandlers ill or infected with communicable diseases, as new 2.11, Work restrictions associated with a food establishment, drug establishment, or cosmetic establishment, and other worksites at which food, drugs, or cosmetics are handled. The Department proposes

new subsection (a), indicating that a person who works at a food establishment, drug establishment, or cosmetic establishment or is a food employee who is confirmed as or suspected of being ill or infected with a communicable disease, infection or condition shall comply with a directive of the Department or local health agency. The Department proposes to recodify existing subsection (a) as new (b) and amend this subsection to refer to N.J.S.A. 24:15-10, which requires an employer to prohibit a person from working with food, drugs, or cosmetics if the person is, or has been exposed to a person who is, confirmed to be or suspected of being ill with a communicable disease, infection, or condition that is transmissible through food, drugs, and/or cosmetics. The Department proposes to delete existing subsection (b). The Department proposes to amend existing subsection (c) , indicating that the public health authority may condition the removal of a prohibition established pursuant to subsection (a) or (b) upon laboratory testing to determine if the person subject to the prohibition continues to be capable of disease transmission by working in a food establishment, drug establishment, or cosmetic establishment and qualifying the term, “communicable disease,” by the phrase, “that is transmissible through food, drugs, or cosmetics.” Proposed new (c)1 would prohibit removal of a prohibition if a person continued to be capable of transmission of a disease that is transmissible through food, drugs, or cosmetics. The Department proposes to amend existing (d) and (d)1 to indicate the public health authority’s ability to prohibit sale or distribution of food, drugs, or cosmetics that a person manufactured, process, stored, prepared, or served, if the person is ill or infected with, or capable of transmission of a communicable disease, infection, or condition that is transmissible through food, drugs, or cosmetics. The Department

proposes to amend existing (d)2 to delete the term “vehicle” and use the more accurate terms “vector” or “fomite.” Proposed new subsection (e) would reiterate the obligation of an owner, operator or another person in charge of a food establishment, drug establishment, or cosmetic establishment to comply with directives of the Department to exclude persons who are ill or infected with a communicable disease, infection, or condition that is transmissible through food, drugs, or cosmetics from working at a food establishment, drug establishment, or cosmetic establishment.

Proposed new N.J.A.C. 8:57-2.12, School data reporting, would establish data reporting requirements of schools. This subsection indicates that schools must report weekly data to the Department into CDRSS. This data includes (1) student census, (2) number of absent students, (3) reason for each absence, and (4) whether an outbreak of communicable disease, infection, or condition is known or suspected to have occurred, or did occur and if an outbreak did occur, the communicable disease, infection, or condition that was known or suspected to have occurred as an outbreak. The proposed new rule would establish as a permanent requirement the reporting obligation that Executive Directive No. 21-011, Protocols for COVID-19 Reporting for School Settings established requiring schools to report this data. Thus, this is an existing reporting obligation.

Proposed new subsection 8:57-2.13, Nursing home data reporting, would establish data reporting requirements applicable to nursing homes. Proposed new subsection (a) would require each nursing home administrator to ensure that the facility submits data twice weekly to the Department through REDCap, the CDRSS, or a designated successor vendor. This data includes (1) number of residents and staff, (2)

number of residents and staff who received a vaccine for COVID-19, influenza, and RSV as of each reporting date, (3) the number of new cases of a reportable communicable disease, infection, or condition among staff or residents, and (4) whether there was an outbreak of any disease, infection, or condition, known or suspected. Proposed new subsection (b) would state that the CDS would report a failure to meet these reporting requirements to the Office of Health Care Facility Survey and Field Operations of the Department. Proposed new subsection (c) would require the Department to issue written and electronic notice if the platform vendor were to change. Nursing homes began the reporting requirements described in the proposed new rule during the COVID-19 pandemic, and this new rule would make the data reporting permanent.

Subchapter 3

P.L. 2004, c 138, approved September 2, 2004, the "Statewide Immunization Registry Act," codified at N.J.S.A. 26:4-131 through 135, established a Statewide automated and electronic immunization registry. N.J.S.A. 26:4-134i directs the Commissioner to promulgate rules to implement the Statewide Immunization Registry Act. The Department establishes and maintains the New Jersey Immunization Information System (NJIIS) to serve as the Statewide automated and electronic immunization registry that the Statewide Immunization Registry Act requires.

Existing Subchapter 3, The New Jersey Immunization Information System (NJIIS), establishes standards governing the New Jersey Immunization Information System (NJIIS). Existing N.J.A.C. 8:57-3.1, Purpose and scope, establishes the purpose and scope of the chapter. The Department proposes to recodify existing

paragraph (a)1, as new subsection (a). The Department proposes to delete existing paragraphs (a)2 and 3. The Department proposes to delete existing subsection (b). The Department proposes to recodify existing subsection (c) as new (b) and amend the subsection to indicate that the subchapter applies to applicants for NJIIS user and NJIIS site access, and persons serving as NJIIS coordinators, NJIIS sites, NJIIS site administrators, NJIIS users and NJIIS registrants.

The Department proposes to repeal existing N.J.A.C. 8:57-3.2, Incorporated documents. This section identified, and incorporated by reference, forms and publications to which the subchapter referred.

The Department proposes to repeal existing N.J.A.C. 8:57-3.3, Definitions, which establishes definitions of terms the subchapter uses, as the proposed amendments at existing N.J.A.C. 8:57-1.3, proposed for recodification as new 1.2, would establish new and/or relocate existing definitions of terms the subchapter uses.

The Department proposes to recodify and amend existing N.J.A.C. 8:57-3.4, Confidentiality, as new 3.2, Confidentiality. The Department proposes to amend existing subsection(a) to reflect that it addresses individually identifiable information in the NJISS. The Department proposes to amend existing (a)1 to correct a cross-reference and indicate that the Department would maintain registrant confidentiality and, if it disseminates reports using the data therein, it will not release information that can be used to identify registrants. The Department proposes to delete existing (a)2. The Department proposes to recodify existing paragraphs (a)3 and 4 as new (a)2 and 3 and proposes amendments to indicate that information about withdrawn registrants would be available to civil and/or criminal law enforcement authorities and to update a cross-

reference. The Department proposes to amend existing subsection (b) to indicate that all information in the NJIIS is confidential and cross-refer to N.J.S.A. 26:4-137 as a basis of sanctions for improper use of NJIIS information. The Department proposes to amend existing subsection (c) to authorize a health benefit plan to request information about a registrant who is an existing or prior member, customer, or beneficiary.

The Department proposes to recodify existing N.J.A.C. 8:57-3.5, Administration, which establishes NJIIS administrative standards, as new N.J.A.C. 8:57-3.3. The Department proposes to delete existing (a)1. The Department proposes to amend existing subsection (b) to refer to the applicable jurisdiction of an MCHC as governing the NJIIS site it is to coordinate. The Department proposes to add new paragraph (b)1, delete the characterization of records in the NJIIS as "medical" records, and add instead the more generic term, "health" records, and delete the requirement that an NJIIS coordinator conduct oversight activities under VPDP supervision, to indicate that, while an NJIIS coordinator may always consult with the VPDP, VPDP supervision is not required in the conduct of an NJIIS coordinator's routine oversight activities. The Department proposes to recodify existing (b)1 and 2 as new (b)2 and 3. The Department proposes to amend existing subsection (c) to delete the requirement that a request for MCHC information be made by a mailed request. The Department proposes to amend existing subsection (d) to refer to the authority of an NJIIS coordinator rather than the responsibilities of an MCHC office. The Department proposes to reorganize existing (d)1 through 3 as new (d)1 through 7 and proposes amendments to restate the duties of an NJIIS coordinator. These would include identifying the authority of a coordinator to administer NJIIS enrollment, making enrollment eligibility determinations,

ensuring as a precondition to granting access to the NJIIS that applicants for NJIIS enrollment execute the NJIIS User Confidentiality Agreement at Appendix D and undergo NJIIS training, specifying user permissions and access rights, providing NJIIS training, issuing credentials, and auditing compliance with the NJIIS User Confidentiality Agreement.

The Department proposes to recodify existing N.J.A.C. 8:57-3.6, Eligibility to become an authorized user and NJIIS site, as new N.J.A.C. 8:57-3.4, Eligibility to become an NJIIS user and NJIIS site, and proposes amendments to reorganize existing paragraph (a)1 as new (a)1 through 13, and restate the entities that are eligible to become NJIIS users and NJIIS sites using the defined terms, “health care facility,” “health care professional,” “early childhood center,” “IHE,” “EHR vendor,” and “HIE, HIO, and HIN.” The Department proposes to delete existing subsection (b), which describes the Commissioner’s rulemaking authority.

The Department proposes to recodify existing N.J.A.C. 8:57-3.7, Authorized user enrollment requirements, as new N.J.A.C. 8:57-3.5, NJIIS user enrollment eligibility requirements and amend the section to delete paragraph (a)1. The Department proposes to recodify existing paragraphs (a)2 and 3 as new (a)1 and 2. The Department proposes new paragraph (a)3 to require an applicant to be associated with an approved NJIIS site. The section would require an applicant to submit Subchapter 3 Appendix C, User Confidentiality Agreement, which the Department proposes to recodify, with amendments, as new Appendix D, the NJIIS User Confidentiality Agreement form.

The Department proposes to recodify existing N.J.A.C. 8:57-3.8, Authorized user applicant enrollment process, as new 3.6, NJIIS site and NJIIS user applicant enrollment process. The Department proposes to amend existing subsection (a) to delete references to application submission methods and identify the procedures to which an applicant for enrollment must adhere to become an NJIIS site. The section would require an applicant to execute and submit the NJIIS Enrollment Request for New NJIIS Site form, which is an existing form proposed for recodification from Subchapter 3 Appendix A as new Appendix B, and the Interface Enrollment Request Form, which the Department proposes as new Appendix U.

The Department proposes to amend existing subsection (b), which establishes the procedure to which an NJIIS site administrator must adhere to enroll new NJIIS users at the NJIIS site. The Department proposes to delete existing paragraph (b)1. The Department proposes to recodify existing paragraph (b)2 as new (b)1 and amend the paragraph to require the NJIIS site administrator to submit the NJIIS User Enrollment and Training Request form, which is an existing form at N.J.A.C. 8:57-3 Appendix B that the Department proposes to recodify with amendments as new Appendix C. The Department proposes to delete existing (b)2i through vi. The Department proposes to recodify existing (b)3 as new (b)2. The Department proposes to amend existing subsection (c) to delete existing paragraph (c)1 through 4 and identify the procedure to which an NJIIS coordinator is to adhere in reviewing an application for NJIIS site enrollment and allocating the applicable NJIIS access level. Proposed new subsection (d) would establish the procedure to which an NJIIS coordinator is to adhere in reviewing an application for NJIIS user enrollment and allocating the applicable NJIIS

access level. The Department proposes to recodify existing subsection (d) as new (e) with amendments to delete existing paragraph 1 and restate the notice requirements following denial of an application for a requested NJIIS access level. The Department proposes to delete existing subsection (e).

The Department proposes to recodify existing Subchapter 3 Appendix D as new Appendix E, the NJIIS Request for Change of User Security Authorization / Request for Password Reset form, which N.J.A.C. 8:57-3.8, proposed for recodification with amendment as new 3.6, at existing subsection (f) would require an NJIIS coordinator to submit when requesting a change in an NJIIS user's NJIIS access level or password.

The Department proposes to amend existing subsection (g) to indicate that, following an NJIIS coordinator's approval of an NJIIS user applicant's application and designation of the applicant's appropriate NJIIS access level, the applicant's completion of the training that corresponds to the applicant's NJIIS access level is a precondition to the NJIIS coordinator's issuance of NJIIS user access credentials to the applicant. The Department proposes to delete existing paragraph (g)1.

The Department proposes to recodify existing N.J.A.C. 8:57-3.8, Authorized user withdrawal, as new N.J.A.C. 8:57-3.6, Process for NJIIS user and NJIIS site withdrawal; access level change request, to establish the process for withdrawal of an NJIIS site and NJIIS user. The Department proposes to amend subsection (a) to delete existing paragraph (a)1, recodify existing paragraphs (a)2 and 3 as new (a)1 and 2, and add new paragraph (a)3, which would require an applicant intending to report by means of an electronic interface to submit the Interface Enrollment Request Form, which is an

existing form proposed for recodification from existing Subchapter 3 Appendix B as new Appendix C.

The Department proposes to amend existing subsection (b) to indicate that an NJIIS site administrator serves as liaison to the Department with respect to the enrollment of each NJIIS user at an NJIIS site. The Department proposes to delete existing paragraph (b)1 and recodify existing paragraph (b)2 as new (b)1, which would require an NJIIS user to submit a completed User Enrollment and Training Request form, which is an existing form at Subchapter 3 Appendix B that the Department proposes to recodify as new Appendix C. The Department proposes to delete existing paragraph (b)1 and recodify existing paragraph (b)2 as new (b)1, which would require an NJIIS user to submit a completed User Enrollment and Training Request form, which is an existing form proposed for recodification from Subchapter 3 Appendix B as Appendix C. The Department proposes to repeal subparagraphs (b)i through vi, as they are contained within the form itself.

Existing subsection (c) establishes criteria by which an MCHC is to review an application for enrollment as an NJIIS site. The Department proposes to delete existing paragraphs 1 and 2, because review of the NJIIS site application would be conducted consistent with N.J.A.C. 8:57-3.4. Existing (c)3 establishes criteria by which an MCHC is to review an application for enrollment as an NJIIS user. The Department proposes to recodify this paragraph as new subsection (d). The Department proposes to delete existing paragraph (c)4. The Department proposes to recodify existing subsection (d) as new subsection (e) and amend the subsection to reflect that a denial could address an application for access as either an NJIIS site or NJIIS user.

The Department proposes to recodify existing subsections (e) and (f) respectively as new subsections (f) and (g). The Department proposes to amend existing subsection (h) to recodify it as new subsection (i), delete existing (h)1, which refers to a security requirement that is part of the NJIIS, and add new subparagraph (i)1i, which would identify the availability of training information at the NJIIS website.

The Department proposes to recodify existing N.J.A.C. 8:57-3.9, Authorized user access to information, which establishes standards for NJIIS user access to NJIIS information, as new N.J.A.C. 8:57-3.7, NJIIS user access to NJIIS information regarding withdrawn registrants; Department investigation of NJIIS system threats; reinstatement of NJIIS user and NJIIS site access. The Department proposes to amend the section to delete existing subsections (a) through (c) as redundant of existing N.J.A.C. 8:57-3.8, as proposed for recodification with amendment as new 3.6, which would address an NJIIS user's means and level of access to NJIIS information. The Department proposes to recodify existing subsection (d) as new subsection (a) and amend it to indicate that NJIIS users would receive an indication that the record of a registrant who has withdrawn from the NJIIS is inaccessible (hereinafter referred to as an "inactive record").

The Department proposes to recodify existing subsection (e) as new (b), and amend it to indicate that NJIIS user support and assistance is available upon reviewing and selecting from among available support topics under the NJIIS "Submit a Request" heading, and thereupon submitting a completed NJIIS Online Ticketing Intake form at proposed new Appendix F. The Department proposes to recodify existing subsection (e) as new (b), and amend it to indicate that NJIIS user support and assistance is available upon reviewing and selecting from among available support topics under the

NJIIS “Submit a Request” heading, and thereupon submitting a completed NJIIS Online Ticketing Intake form, as proposed new Appendix F. Proposed new subsection (c) would indicate that NJIIS use is subject to audit by the Department and the applicable NJIIS coordinator. Proposed new subsection (d) would establish the duty of each NJIIS user and NJIIS site to cooperate with, and provide information and documentation upon request to, the Department and the applicable NJIIS coordinator in support of NJIIS audit and oversight activities. Proposed new subsection (e) would identify the authority of the Department to suspend NJIIS access to address NJIIS system threats and deny and/or impose conditions on reinstatement of access, depending on the result of the Department’s investigation of the threat.

The Department proposes to recodify existing N.J.A.C. 8:57-3.10, Authorized user withdrawal, which establishes procedures by which an NJIIS site administrator can request the withdrawal or change of an NJIIS user or NJIIS site’s access, as new N.J.A.C. 8:57-3.8, Process for NJIIS user and NJIIS site withdrawal; access level change request. The Department proposes to amend the section to indicate that an NJIIS site administrator, rather than the NJIIS or the VPDP, is to process such requests, using the NJIIS Request for Change of User Security Authorization/Request for Password Reset form at Appendix E. The Department proposes to delete subsection (b), which establishes the timeline within which the VPDP is to address these requests.

The Department proposes to recodify existing N.J.A.C. 8:57-3.11, Informing parents, which establishes standards for notifying parents about the NJIIS, as new N.J.A.C. 8:57-3.9, Informing parents of newborns about the NJIIS pursuant to N.J.S.A. 26:4-134(i)3. The Department proposes to amend the section to delete existing

subsection (a). The Department proposes to recodify existing subsection (b) as new (a) and amend the subsection to delete existing paragraphs 1 through 4, and to require a birthing facility to establish procedures to ensure that the parent of a newborn receives the NJIIS Informational Brochure. The Department proposes to recodify existing subsection (c) as new (b) and amend the subsection to delete existing paragraph 2 and indicate that a healthcare professional providing care to a minor who is not enrolled in the NJIIS is to make the NJIIS Informational Brochure available to the minor's parent, in either a paper or electronic format.

The Department proposes to recodify existing N.J.A.C. 8:57-3.12, Registrant enrollment, which establishes procedures by which to enroll a person in the NJIIS, as new N.J.A.C. 8:57-3.10, Registrant enrollment. Existing subsection (a) reflects the Department's reconfiguration of the NJIIS system as of January 1, 1998, to enroll every newborn upon a birthing facility's creation of that newborn's electronic birth certificate. The Department proposes to amend subsection (a) to delete the reference to the 1998 reconfiguration of the NJIIS and the description of a procedure by which a parent can preemptively prevent a newborn's enrollment. Pursuant to N.J.S.A. 26:4-134, enrolled adults who do not want their immunization records, and parents who do not want their minor children's immunization records, to appear in the NJIIS must affirmatively request that the immunization records be made inactive in accordance with the procedure at N.J.A.C. 8:57-3.15, as proposed for recodification with amendment as new 3.13, described below.

Subsection (b) would require the use of the Request for Change to NJIIS Immunization Record form, which is an existing form at Subchapter 3 Appendix H,

proposed for recodification as new Appendix H. The Department proposes to amend existing subsection (d) to indicate that a healthcare professional treating a minor who does not appear as enrolled in the NJIIS (typically one born in another jurisdiction) is to register the minor in the NJIIS, unless the minor's record appears as an inactive record, thereby indicating the parent's withdrawal of the minor's participation in the NJIIS pursuant to N.J.A.C. 8:57-3.13, as proposed for recodification from existing 3.15. The Department proposes to delete existing subsection (e) and reorganize existing paragraphs (e)1 and 2 as new subsection (e), to provide the instructions by which a non-enrolled person can obtain NJIIS enrollment through paper or electronic submission to an NJIIS user of an executed form of NJIIS Consent to Participate, which is an existing form incorporated by reference at Subchapter 3 Appendix F that the Department proposes to recodify as new Appendix G..

The Department proposes to amend existing subsection (f) to indicate that an NJIIS user described at proposed new subsection (e) is to enroll a person upon receiving a request pursuant to proposed new subsection (e). The Department proposes to delete existing subsection (g) as redundant of proposed new subsection (e) and (f). The Department proposes to recodify existing (g)1 as new subsection (g) and amend the subsection to indicate that withdrawal of a person from NJIIS participation does not affect the obligation of an administrator to exclude that person from attendance at a child care center, a school, or an IHE, if the person does not provide evidence of immunity or immunization pursuant to N.J.A.C. 8:57-4 and 6. The Department proposes to recodify existing paragraph (g)2 as new subsection (h) and amend the subsection to indicate that one can reenroll in NJIIS after having withdrawn from participation therein,

by adhering to the enrollment procedure at proposed new subsection (e). The Department proposes to delete existing subsections (h) and (i) as redundant of existing N.J.S.A. 26:4-136.

The Department proposes to recodify existing N.J.A.C. 8:57-3.13, Registrant access to information, which establishes standards by which registrants can obtain their NJIIS records, as new N.J.A.C. 8:57-3.11, Registrant access to registrant's NJIIS information. The Department proposes to amend subsection (a) to indicate that a registrant can obtain a printout of the registrant's NJIIS record by (1) making a request to a healthcare professional who is an NJIIS user, (2) submitting a completed NJIIS Request for NJIIS Immunization Record to the VPDP, which is an existing form at Subchapter 3, Appendix I, proposed for recodification as new Appendix I, or (3) at proposed new (a)3, using the Docket® mobile application or website, or a successor application administered by an entity with which the Department may elect to enter into a cooperative data-sharing agreement. The Department proposes to delete existing subsection (b), which establishes a blanket deadline for responses to requests. Although fulfillment of a request can be made upon receipt, the Department anticipates that a healthcare professional will fulfill a request by no later than the time that State and Federal standards establish for response to a patient request for other health records. The VPDP would continue to respond to these requests upon receipt, as staffing and other resources permit.

N.J.S.A. 26:4-134i(4) requires the Department to establish procedures by which one can "review and correct information contained in the [NJIIS]." The Department proposes to recodify existing N.J.A.C. 8:57-3.14, Registrant amendment of record,

which establishes standards by which a registrant can request a change to the registrant's NJIIS record, as new N.J.A.C. 8:57-3.12, Registrant amendment of NJIIS record. The Department proposes to amend subsection (a) to indicate that a registrant can request a change in accordance with procedures the registrant's healthcare professional establishes, if the healthcare professional is an NJIIS user, and require a healthcare professional who is an NJIIS user to memorialize a change request and related information in the registrant's NJIIS record and notify the requester of the opportunity to seek VPDP reconsideration of a denied change request. The Department proposes to reorganize existing paragraph (a)1 as new subsection (b) with amendment to establish that a registrant can submit an NJIIS record change request to the VPDP if the registrant's healthcare professional either denies a change request or is not an NJIIS user. The Department proposes to delete existing paragraph (a)2. The Department proposes to recodify existing subsection (b) as new (c) and delete existing subsection (c). The Department proposes to delete existing subsection (f), which establishes an opportunity for rebuttal of a statement of a requester's disagreement with a decision not to change an NJIIS record. The Department anticipates that the statement that the VPDP would issue to explain its rationale for not making a requested change, pursuant to existing subsection (e), would be sufficient to establish its position without need for additional rebuttal. The Department proposes to delete existing subsection (i), which requires a healthcare professional to send documentation supporting denied change requests to the VPDP and establishes a procedure for VPDP review of an NJIIS user's denial of a change request. These standards are unnecessary because the proposed amendment at subsection (a) would require an

NJIIS user to memorialize in the NJIIS a requested change and the documentation submitted in support of the change request, to which the VPDP has access, and the proposed amendment at subsection (b) would establish an opportunity for a requester to submit a denied change request to the VPDP for *de novo* review.

N.J.S.A. 26:4-134i(5) requires the Department to establish procedures by which one can "request to not participate in the [NJIIS] and to remove or inactivate information from the [NJIIS]." The Department proposes to recodify existing N.J.A.C. 8:57-3.15, Registrant withdrawal, which establishes procedures by which a registrant can withdraw from participation in the NJIIS and can re-enroll following a withdrawal, as new N.J.A.C. 8:57-3.13, NJIIS registrant withdrawal; reenrollment. Subsection (a) would require a requester to use the NJIIS Registrant Withdrawal from NJIIS form, which is an existing form incorporated by reference at Subchapter 3 Appendix J, proposed for recodification as new Appendix J. The Department proposes to amend existing subsection (b) to extend from three to five business days the time within which the VPDP is to respond to a withdrawal request and indicate that the NJIIS shows the record of a withdrawn registrant as inactive due to the registrant's withdrawal from participation. This is necessary to prevent inadvertent reenrollment by health care facilities and healthcare professionals, who would have patient enrollment and reporting obligations pursuant to N.J.A.C. 8:57-3.10 and 3.14, as proposed for recodification and amendment, following a health care encounter with a patient who has withdrawn from participation. The Department proposes to amend existing subsection (c) by cross-referring to the procedure by which a withdrawn participant can reenroll in the NJIIS at N.J.A.C. 8:57-3.12, as proposed for recodification with amendment as new 3.10.

The Department proposes to recodify existing N.J.A.C. 8:57-3.16, Mandatory participation for health care providers, which establishes standards requiring mandatory participation in the NJIIS, as new N.J.A.C. 8:57-3.14, Mandatory NJIIS participation of healthcare professionals. The Department proposes to delete references throughout the section to the term, "health care provider," and add in place thereof references to the defined term, "healthcare professional," and delete references throughout the section to NJIIS participation and reporting by birthing facilities as redundant, because N.J.A.C. 8:57-3.10, as proposed for recodification with amendment from 3.12, addresses each birthing facility's obligation to enroll every newborn upon birth through completion of the EBC.

Existing subsection (a) limits the obligation of a healthcare professional to participate in the NJIIS to those who provide immunizations to patients under age seven. Existing N.J.A.C. 8:57-3.12, proposed for recodification as new 3.10, at subsection (d), which requires every healthcare professional who provides health care to a minor who is not enrolled in the NJIIS to enroll the minor in the NJIIS, has been in effect since October 19, 2009. 40 N.J.R. 5908(a), 41 N.J.R. 3899(c). Thus, there is no basis to limit the obligation of a healthcare professional to become an NJIIS user to those who vaccinate minors under age seven, because a healthcare professional who treats any minor is subject to an existing obligation to ensure that the minor is enrolled in the NJIIS, and to do so, the healthcare professional must be at least an NJIIS user, if not an NJIIS site. Therefore, the Department proposes to amend existing subsection (a) to require each healthcare professional who provides health care to a minor to become, an NJIIS user and, subject to proposed new subsection (h), an NJIIS site, and

report each vaccination administration to a minor in accordance with subsections (d) through (f), as proposed for amendment.

The experience of the Department and the State during the COVID-19 public health emergency and recent natural disasters that resulted in family displacements from other USA states and territories to New Jersey have demonstrated the benefit to the State and the public of the NJIIS as a Statewide resource to document the immunization status of all New Jerseyans. For example, during the COVID-19 public health emergency, the mobile telephone application, Docket®, which sources its content from NJIIS data, enabled users to readily demonstrate evidence of their immunization status and thereby obtain admission to places of public accommodation that conditioned entry upon proof of immunization. NJIIS data also enabled the Department to configure regional mapping of under-immunized populations and thereby appropriately direct its COVID-19 vaccination outreach efforts to those potential contagion “hot spots.” Moreover, the NJIIS is a lifespan registry that facilitates the recreation of health records when records stored in other locations are lost or destroyed, such as in natural disasters, and helps families who are thereby displaced to avoid repeat vaccinations when their paper records are lost. The NJIIS’s ability to share and receive data through interconnectivity with other states’ immunization registries enables families who relocate to or from other jurisdictions to easily retrieve their immunization records.

Given the many benefits that the NJIIS affords the State and its people, the Department is proposing to require all healthcare professionals who administer vaccines to adults to become NJIIS sites and NJIIS users, and to report immunizations administered to adults, in addition to their existing obligation to report immunizations

administered to minors. Adults, and minors through their parents, would retain the ability to withdraw from participation in the NJIIS in accordance with the procedure at N.J.A.C. 8:57-3.15, as proposed for recodification with amendment as new 3.13.

Executive Order 207, which Governor Murphy issued on December 4, 2020, requires every entity, including healthcare professionals, administering COVID-19 vaccinations to persons of any age to enroll unenrolled persons into the NJIIS, and to report the administration of COVID-19 vaccinations to those persons to the NJIIS. Therefore, the Department anticipates that healthcare professionals who administered COVID-19 vaccinations during the public health emergency will have already become NJIIS sites and/or NJIIS users to comply with Executive Order 207, and that the obligation to become NJIIS sites and/or NJIIS users would impose a new requirement only on healthcare professionals that newly elect to administer immunizations to adults.

The ACIP recommendations for childhood immunizations apply to persons from birth through age 18, that is, until the 19th birthday. The ACIP recommendations for adult immunizations apply to persons from age 19 and above. To ensure that the NJIIS captures immunizations that healthcare professionals administer to non-minors pursuant to the childhood immunization ACIP recommendations, the Department proposes to amend existing subsection (b) to require a healthcare professional who administers a vaccine to a person who has attained the 18th birthday but is under age 19 to become an NJIIS site and NJIIS user, and thereupon commence reporting in accordance with subsections (d) through (f), within one year of the effective date of the section, as proposed for amendment. To capture immunizations administered to persons pursuant to the adult ACIP recommendations, the Department proposes new

subsection (c) to require a healthcare professional who administers an immunization to a person of any age to become an NJIIS site and NJIIS user, and thereupon commence reporting in accordance with subsections (d) through (f), within 545 days (one year plus 180 days, or roughly a year and a half) of the effective date of the section.

The Department proposes to reorganize content from existing subsection (b) as new subsection (d) to reflect that some healthcare professionals fulfill their reporting obligations by entering individual patient information directly to the NJIIS and others by reporting to the NJIIS through vendor software and/or services. The Department proposes to delete existing subsection (c). The Department proposes to recodify existing subsection (d), which identifies information that healthcare professionals are to report, as new (e), and proposes amendments to correct the list of required data fields that a healthcare professional must report to the NJIIS. The Department proposes to delete as unnecessary existing subsection (e) which restates healthcare providers' reporting responsibility, regardless of any delegation. The Department proposes to amend existing subsection (f) to require, rather than suggest, that a healthcare professional submit missing information required pursuant to subsection (e) or correct inaccurate information in a registrant's NJIIS record, to the extent the correct information is available The Department proposes to amend existing subsection (g) to require a healthcare professional who is not an NJIIS user to correct or update a registrant's NJIIS record by submitting information to the VPDP using the paper Request for Change to NJIIS Immunization Record form at Appendix H. Proposed new subsection (h) would exempt a healthcare professional who is subject to subsections (a), (b), or (c) from the obligation to become an NJIIS site if the healthcare professional

has NJIIS user status at an existing NJIIS site and at an NJIIS access level that enables the healthcare professional to report in full compliance with subsections (d) through (f).

The Department proposes to repeal existing N.J.A.C. 8:57-3.17, Application of the NJIIS tracking/reminder recall function, because it does not reflect existing NJIIS operations. The Department proposes to repeal existing N.J.A.C. 8:57-3.18, Acceptance of NJIIS record as evidence of immunization, because N.J.S.A. 8:57-4 and 6, as proposed for amendment, would address evidence of immunization.

The Department proposes to recodify existing N.J.A.C. 8:57-3.19, Data exchange, as new N.J.A.C. 8:57-3.15, Data exchange, and proposes to amend the section to indicate that the Department may engage in immunization data interchange with immunization registries that another state or region recognizes as official pursuant to the health oversight function of that state or region, in accordance with standards of the American Immunization Registry Association *Public Health Immunization Information System Interjurisdictional Memorandum of Understanding* and in accordance with the NJIIS Interface Implementation Guide, which establishes the minimum required criteria for NJIIS data exchange policies for the NJIIS. The Department proposes to delete existing paragraphs (b)1 through 3. Proposed new subsection (d) would indicate that the VPDP would defer to the processes and procedures of the sending entity with respect to data it receives from registries outside of New Jersey.

The Department proposes to recodify existing N.J.A.C. 8:57-3.20, Reports, which addresses reports that the Department issues using data from the NJIIS, as new N.J.A.C. 8:57-3.16, Reports pursuant to N.J.S.A. 26:4-134(i)8. The Department

proposes to amend the section to cross-refer to N.J.S.A. 26:4-134(i)8 in the section heading. The Department proposes to amend subsection (a) to delete text that is redundant of that statute. The Department proposes to delete existing subsections (b) through (d), which unnecessarily describe reports that the Department may issue pursuant to N.J.S.A. 26:4-137. The Department proposes to recodify existing subsection (e) as new (b) and amend it to indicate that information contained in the NJIIS is confidential pursuant to N.J.S.A. 26:4-137.

The Department proposes to repeal existing N.J.A.C. 8:57-3.21, Authorized user immunity, because it is redundant of N.J.S.A. 26:4-135.

The Department proposes to recodify existing N.J.A.C. 8:57-3.22, Penalties, which addresses sanctions that are available for improper activity relating to the NJIIS, as new N.J.A.C. 8:57-3.17, Enforcement, and amend the section to include noncompliance with the Statewide Immunization Registry Act, N.J.S.A. 26:131 et seq., as being subject to sanction; cross-refer to N.J.S.A. 26:4-137 and N.J.A.C. 8:57-1.4, which identify available sanctions; delete specific descriptions of offenses; and identify generally the Department's option of referring improper activity relating to the NJIIS to applicable regulatory entities with jurisdiction and facility administrators. The Department proposes to delete existing subsections (b) and (c) because the applicable enforcement provisions are described above.

The Department proposes to repeal existing N.J.A.C. 8:57-3.23, Appeals, which addresses appeals.

Subchapter 4

N.J.S.A. 26:1A-7 authorizes the Public Health Council to establish, amend, and repeal "reasonable sanitary regulations not inconsistent with [N.J.S.A. 26:1A-1 et seq.] or … any other law of this State as may be necessary properly to preserve and improve the public health in this State. The regulations so established shall be called the State Sanitary Code. The State Sanitary Code may cover any subject affecting public health, or the preservation and improvement of public health and the prevention of disease in the State …, including the immunization against disease of all school children in the State …." As described above, the Reorganization Plan operated to allocate the rulemaking authority of the Public Health Council to the Department. In accordance with the Reorganization Plan, the Department makes this proposal in consultation with the Public Health Council.

N.J.S.A. 26:1A-9 states, in part, that "the State Sanitary Code shall have the force and effect of law[,] shall be observed throughout the State and shall be enforced by each local board of health, the local police authorities and other enforcement agencies" and that "[e]very person[,] organization[,] or board of education having control of any public or private school in this State shall insure compliance with the State Sanitary Code as it pertains to the immunization against disease of children attending or having the right to attend such school, including any provision of the code which prohibits attendance by a child who has not been immunized."

N.J.S.A. 26:1A-9.1 states, "[p]rovisions in the State Sanitary Code in implementation of this act shall provide for exemption for pupils from mandatory immunization if the parent or guardian of the pupil objects thereto in a written statement

signed by the parent or guardian upon the ground that the proposed immunization interferes with the free exercise of the pupil's religious rights. This exemption may be suspended by the State Commissioner of Health during the existence of an emergency as determined by the State Commissioner of Health."

N.J.S.A. 26:2-137.1, in part, directs the Department "to specify [through rulemaking, the] childhood immunizations recommended by the Advisory Committee on Immunization Practices of the United States Public Health Service and the Department of Health."

N.J.S.A. 26:4-6 states, "[a]ny body having control of a school may, on account of the prevalence of any communicable disease, or to prevent the spread of communicable diseases, prohibit the attendance of any teacher or pupil of any school under their control and specify the time during which the teacher or scholar shall remain away from school."

N.J.S.A. 18A:40-21.1 states, "[t]he Commissioner of Health shall require the immunization of a child for hepatitis B as a condition of enrollment in grades nine through 12"; prohibits principals, directors, and other persons in charge of public or private schools in the State from "knowingly admit[ting] or retain[ing] in grades nine through 12 a child whose parent or guardian has not submitted acceptable evidence of the child's immunization for hepatitis B prior to or during enrollment in ninth grade, as provided by regulation of the Commissioner of Health," and directs the Commissioner to promulgate rules implementing this law.

Existing Subchapter 4, Immunization of Pupils in School, implements the rulemaking obligations of the Department pursuant to the laws identified above. The

Department proposes to amend the heading of the subchapter to be Subchapter 4, Immunization of Children in Child Care Centers and Schools.

The Department proposes to amend existing N.J.A.C. 8:57-4.1, Applicability, to be N.J.A.C. 8:57-4.1, Scope, and to reflect at new subsection (a) that the subchapter does not impose direct obligations on minors. Rather, the subchapter establishes the obligations of administrators of schools and child care centers, consistent with the laws described above that impose obligations on persons in charge of such facilities, to exclude from attendance persons who do not present evidence of immunization against or immunity to the vaccine-preventable diseases the subchapter identifies. Proposed new subsection (b) would indicate that, within the subchapter, the term, "facility" would refer collectively to schools and child care centers. Proposed new subsection (c) would state that, notwithstanding a person's claim of a religious exemption, the subchapter would not limit a private facility's authority to exclude a person from attendance who has not received an immunization that this subchapter requires or an additional immunization that is consistent with ACIP recommendations.

The Department proposes to amend existing N.J.A.C. 8:57-4.2, Proof of immunization, to be N.J.A.C. 8:57-4.2, Administrator to require evidence of immunization or immunity, to indicate that the section addresses an administrator's obligation to require evidence of immunization or immunity. Proposed new N.J.A.C. 8:57-4.2(a) would require an administrator to require evidence of a minor's immunization pursuant to N.J.A.C. 8:57-4.3 and 4.4, as proposed for amendment, and/or evidence of a minor's immunity pursuant to N.J.A.C. 8:57-4.5, subject to the existence of a medical contraindication pursuant to N.J.A.C. 8:57-4.7, a religious

exemption pursuant to N.J.A.C. 8:57-4.8, and compliance with immunization standards in effect prior to the effective date of the proposed amendments, as specified in proposed new N.J.A.C. 8:57-4.2(d) through (f). N.J.A.C. 8:57-4.2, as proposed for amendment, would require an administrator to obtain evidence of a minor's immunization or immunity, as a condition of the minor's continued enrollment in the facility and would require the use of the Standard School/Child Care Center Immunization Record form at proposed new Appendix K, which contains fields for each immunization as to which an administrator is to require evidence of a minor's immunization or immunity.

Proposed new subsection (b) would establish that an administrator is to adhere to the ACIP recommendations in determining whether the evidence presented on behalf of a minor is acceptable with respect to the timing of doses, the criteria for a determination of immunity, and the validity of a medical contraindication. The Department proposes to amend existing subchapter (c) to refer to evidence of immunity pursuant to subsection (a). Proposed new subsection (d) would refer to the McKinney-Venton Homeless Assistance Act at 42 U.S.C. §§ 11431-11435, and N.J.A.C. 6A:32, and provide a 10-day grace-period for the transfer of a minor's immunization record from a previously attended New Jersey public or private school or other facility, during which an administrator is to admit the minor's to the facility. Proposed new subsection (e) would make the subchapter apply prospectively by authorizing an administrator to recognize, as valid, doses of certain vaccines that were administered on dates that were inconsistent with ACIP recommendations for minimum age and dose intervals if these were administered in accordance with rules in effect as of their administration, and prior

to the effective dates of the proposed amendments to the subchapter. Proposed new subsection (f) similarly would authorize an administrator to recognize, as valid, untimely administered doses of the following, if administered prior to January 7, 2008, which was the effective date of amendments to the chapter that were consistent with then-existing ACIP recommendations for minimum age and dose intervals for the following: measles, mumps, and rubella; hepatitis B; pneumococcal conjugate vaccine; *Haemophilus influenzae* type B; and varicella. See 38 N.J.R. 5284(a), 40 N.J.R. 151(a).

Proposed new N.J.A.C. 8:57-4.3, Immunizations as to which an administrator shall require evidence, would identify the vaccines as to which an administrator is to require evidence of immunization or immunity pursuant to N.J.A.C. 8:57-4.2 and the ACIP recommendations. Proposed new subsections (a) and (c) would establish the vaccines to be required as a condition of admittance to, respectively, a child care center, and a school. Subsection (a) would require a child care center administrator to require evidence of a minor's immunization, in accordance with the ACIP recommendations, with the following vaccines, or immunity to the diseases corresponding thereto: DTaP, Hib, PCV, polio virus, influenza, MMR, and VAR. Proposed new subsection (b) would require a child care center administrator to accept, as an alternative to evidence of a minor's immunity to, or immunization in accordance with the ACIP recommendations schedule against, influenza, evidence of a minor's immunization by November 30 of each year with one dose of the applicable influenza vaccine that is formulated for each influenza season as announced by the CDC. Proposed new subsection (c) would require a school administrator to require evidence of a minor's immunization, in accordance with the ACIP recommendations, with the

following vaccines, or immunity to the diseases corresponding thereto: DTaP, Td, or Tdap; Hep B; IPV or OPV; MMR; VAR; and Meningococcal serogroups A, C, W, Y vaccine (MenACWY). Proposed new subsection (d) would authorize an administrator to accept evidence of a minor having received at least one dose of varicella vaccine, instead of requiring adherence to the ACIP recommendations as to the number of varicella vaccine doses. Proposed new subsection (e) would authorize an administrator to accept evidence of a minor having received at least one dose of the MenACWY vaccine, instead of requiring adherence to the ACIP recommendations as to the number of MenACWY vaccine doses. Proposed new subsection (f) would oblige an administrator to require evidence of a minor having received the doses of DTaP, IPV or OPV, and MMR vaccines that the ACIP recommendations categorize as due during the ages of four through six years of age prior to the minor's first attendance at kindergarten or a higher grade, depending on which occurs first.

The Department proposes to recodify existing N.J.A.C. 8:57-4.6, Documents accepted as evidence of immunization, as new N.J.A.C. 8:57-4.4, Evidence of immunization. The Department proposes to amend existing subsection (a) to cross-refer to an administrator's obligation to require evidence of immunization at N.J.A.C. 8:57-4.2, as proposed for amendment, the immunizations as to which administrators are to require evidence at proposed new N.J.A.C. 8:57-4.3, and administrators' recordkeeping obligations pursuant to proposed new N.J.A.C. 8:57-4.6, described below; and indicate that evidence of immunization can consist of more than one of the acceptable forms of documentation if the documents, viewed alone or in combination, identify the month, day, and year of administration of each required dose, or only the

month and year, if the totality of the documentation enables the administrator to comply with proposed new subsection (c). The Department proposes to reorganize existing (a)1 through 4 as new (b)1 through 5. A proposed amendment at new (b)1 would specify that the official facility record may consist of an electronic health record. A proposed amendment at new (b)2 would identify health authority records issued by the government of the USA as acceptable forms of evidence. A proposed amendment at new (b)3 would change the undefined term, “certificate,” to “record,” and would delete text that would be redundant of the definition of the term, “health care professional,” at N.J.A.C. 8:57-1.3, as proposed for recodification with amendment as new N.J.A.C. 8:57-1.2. The Department proposes to amend proposed new (b)4 to delete text that restates the required content of a record, which subsection (a), as proposed for amendment, would address, and to identify a record from the Docket® application or website, or a successor application, as an official NJIIS record. A proposed amendment at new (b)5 would identify records issued by a foreign health services provider and a foreign government agency as acceptable forms of evidence, provided that, if the record is in a language other than English, it is accompanied by an English translation that the translator certifies, under the penalty of perjury, to be true, accurate, and complete. The Department proposes to delete existing subsection (c), which addresses immunity from disease, because proposed new N.J.A.C. 8:57-4.5 would address this topic. Proposed new subsection (c) would identify the analysis that an administrator is to undertake in reviewing submitted evidence of immunization, that is, to confirm that the evidence shows that a minor received valid doses of required immunizations in accordance with N.J.A.C. 8:57-4.2 and 4.3.

The Department proposes to repeal existing N.J.A.C. 8:57-4.5.

As described above, proposed new N.J.A.C. 8:57-4.2(a)2 would require an administrator to accept evidence of a minor's immunity to a vaccine-preventable disease, as an alternative to requiring evidence of the minor's immunization against that disease. Proposed new N.J.A.C. 8:57-4.5, Evidence of immunity, would identify records that an administrator is to accept as evidence of a minor's immunity to vaccine-preventable diseases, provided the evidence is consistent with the ACIP recommendations as to schedules, laboratory testing, and other indicators of positive immunity. Paragraph (a)1 would identify conditions as to which a positive serologic test is evidence of immunity, which are measles, mumps, rubella, varicella, and poliomyelitis virus types one, two and three. Paragraph (a)2 would identify positive surface antibody or antigen laboratory test results as indicative, respectively, of immunity to or ongoing infection with hepatitis B. Paragraph (a)3 would establish that a record signed by one of the indicated health care professionals stating that the professional diagnosed or verified that the minor had chicken pox is evidence of immunity that obviates the need for varicella vaccination. Subsection (b) would implement "Holly's Law," N.J.S.A. 26:2N-9, which requires an administrator to accept a positive serologic test, also known as an antibody titer, in lieu of requiring evidence of a minor's receipt of the second dose of the measles, mumps, and rubella vaccine in accordance with the ACIP recommendations.

Proposed new N.J.A.C. 8:57-4.6, Administrator obligations with respect to documentation of compliance and recordkeeping, would establish the obligations of an administrator with respect to documentation of compliance and recordkeeping. Subsection (a) would require an administrator to establish a discrete file for each minor

to whom the administrator grants and/or denies admission or enrollment to a facility, to maintain the file separately from a minor's medical and educational records, and to make the file available for inspection on request of a local health official with jurisdiction and the Department, for auditing and related public health oversight and enforcement activities. Subsection (b) would require an administrator to maintain original paper records of immunization, immunity, or exemption evidence submitted on behalf of a minor, regardless of whether the administrator also elects to maintain the records in an electronic form, and would indicate that the Department will treat material generated from electronically stored records to be supplemental to, and not as a substitute for, an original record. Subsection (c) would identify the file that an administrator creates pursuant to proposed new subsection (a) to be the minor's "immunization record" as the Department of Education construes that term and would cross-refer to rules of that Department at N.J.A.C. 6A:16-2.4, Required student health records, and 6A:32-7, Student Records, which establish standards relating to the establishment and handling of such records, such as access, retention, transfer and disposal.

The Department proposes to repeal existing N.J.A.C. 8:57-4.7, Records required, because N.J.A.C. 8:57-4.6 would address these matters.

The Department proposes to recodify existing N.J.A.C. 8:57-4.3, Medical exemptions, as new N.J.A.C. 8:57-4.7, Exemption due to medical contraindication; required documentation; administrator review. The Department proposes to amend existing subsection (a) to indicate that the section imposes obligations on an administrator, not a minor, and prohibits an administrator from requiring evidence of a minor's immunization against or immunity from the vaccine-preventable conditions

specified at N.J.A.C. 8:57-4.3 if the immunization is medically contraindicated or presents as a medical precaution for the minor for a reason that the ACIP recommendations identify as a vaccine contraindication or precaution. The Department proposes to amend existing subsection (b) to identify the evidence an administrator is to require in support of an exemption based on medical contraindication or precaution, that is, a statement from one of the indicated health care professionals that identifies the vaccine that presents a contraindication or precaution, the period during which the contraindication or precaution exists, and the reason that the vaccine is contraindicated or presents a precaution for the minor. N.J.A.C. 8:57-4.7 would prohibits an administrator from requiring evidence of a minor's immunization pursuant to N.J.A.C. 8:57-4.2 when an immunization is medically contraindicated for a minor or as a precaution when the risk for adverse reaction outweighs its medical benefit. In these cases, the rule would require an administrator to require submission on the minor's behalf of the Request for Medical Exemption from Mandatory Immunization form at Appendix L, signed by one of the indicated health care professionals who identifies the applicable contraindication or precaution.

The Department proposes to delete existing subparagraph (b)1 as redundant of the defined term "ACIP recommendations" at N.J.A.C. 8:57-1.2, as proposed for amendment and recodification from N.J.A.C. 8:57-1.3. The Department proposes to amend existing subsection (c) to indicate that the subsection would oblige an administrator to review both the statement for compliance with subsections (a) and (b), in consultation with the VPDP if necessary, and a granted exemption by the earlier of either the end of the specified period of exemption or annually to ensure that upon the

conclusion of a period of contraindication or precaution the administrator requires evidence of the minor's immunization or immunity in accordance with N.J.A.C. 8:57-4.2, as proposed for amendment, and applicable ACIP recommendations. The Department proposes to delete existing subsections (d) and (e) as redundant of proposed new N.J.A.C. 8:57-4.10, discussed below.

The Department proposes to recodify existing N.J.A.C. 8:57-4.4, Religious exemptions, as new N.J.A.C. 8:57-4.8, Religious exemption. Existing statutes that authorize administrators to admit and enroll unimmunized and non-immune minors vary depending on the facility to which a minor seeks admission. N.J.S.A. 30:5B-5 states, with respect to licensure of a child care center, that rules "involving … immunization … shall [exempt] any child whose parent or parents object thereto on the ground that it conflicts with the tenets and practice of a recognized church or religious denomination of which the parent or child is and adherent or member." The Department proposes to amend existing subsection (a) to implement this requirement as applicable to a child care center administrator. N.J.S.A. 26:1A-9.1 exempts "pupils from mandatory immunization if the parent or guardian of the pupil objects thereto … upon the ground that the proposed immunization interferes with the free exercise of the pupil's religious rights." Proposed new subsection (b) would implement this requirement as applicable to a school administrator. Proposed new subsection (c) would establish the documentation that the administrator of a child care center or school is to require in support of a request for exemption on religious grounds. Proposed new subsection (d) would reflect the ineligibility of moral or philosophical objections as a basis for religious exemption from required vaccinations. Proposed new subsection (e) would require an

administrator to secure evidence of immunization or immunity as to those required immunizations to which religious exemption on the minor's behalf is not submitted.

In deference to a religious-affiliated institution's authority and expertise to determine whether the religion with which the institution affiliates recognizes the receipt of a specific vaccine as conflicting or interfering with that religion, proposed new subsection (f), to be recodified from existing subsection (b), would reflect the authority of the administrator of a religious-affiliated institution to grant a request for religious exemption without challenge by a secular health authority. Proposed new subsection (g), to be recodified from existing subsection (c), would establish an administrator's record-retention duties with respect to the written statement submitted on a minor's behalf in support of a religious exemption request. The Department proposes to delete existing subsections (d) and (e). Proposed new subsection (h), to be recodified from existing subsection (f), would indicate that an administrator is not to require annual resubmission of a religious exemption request that appears of record. Proposed new subsection (i) would require an administrator to deem withdrawn a religious exemption of record if the minor, with a parent's consent, obtains an immunization in contravention of the assertion contained in the written statement submitted in support of the religious exemption, and to require submission a new request for a religious exemption if the reinstatement of the exemption is sought with respect to subsequent vaccine doses of which this chapter would require evidence of the minor's receipt.

The Department proposes to repeal existing N.J.A.C. 8:57-4.9, Records available for inspection, and adoption of a new rule at N.J.A.C. 8:57-4.9, Provisional and foreign admission. Subsection (a) would establish conditions under which an administrator is to

admit and/or continue the enrollment of a minor, to whom applicable ACIP recommendations apply, who is missing vaccinations, or unable to present evidence of immunizations or immunity to vaccine-preventable diseases. Subject to subsection (b), subsection (a) would require an administrator to require submission of evidence that the minor has received at least one dose of the missing immunization and is no later than 14 days behind an applicable Catch-up Schedule in receiving any remaining required doses. Subsection (b) would establish conditions under which an administrator is to admit and/or continue the enrollment of a minor from outside the United States of America for no longer than 30 days, if, during that period, evidence is submitted of the minor's required immunization or immunity, or that that minor has received at least one dose of a missing immunization and is no later than 14 days behind an applicable Catch-up Schedule in receiving any remaining required doses.

Effective January 17, 2010, New Jersey "enacted and entered into" the "Interstate Compact on Educational Opportunity for Military Children" (compact), which the Military Interstate Children's Compact Commission (MIC3) originally promulgated in 2009. N.J.S.A. 18A:75A-1; https://mic3.net. The purpose of the compact is "to remove barriers to educational success imposed on children of military families because of frequent moves and deployment of their parents," by facilitating, among other things, "the timely enrollment of children of military families and ensuring that they are not placed at a disadvantage due to difficulty in the transfer of education records from the previous school district or districts." N.J.S.A. 18A:75A-2(a). N.J.S.A. 18A:75A-4 identifies the minors to whom the compact applies by reference to the status of their parents as members of the uniformed services. N.J.S.A. 18A:75A-5(c) is consistent

with existing MIC3 compact rule § 3.102(a), in providing 30 days from the date of enrollment within which a parent is to submit evidence of a minor's immunization or immunity, and/or having obtained an initial vaccination with respect to an immunization series. See MIC3, Interstate Compact on Educational Opportunity for Military Children, Third Edition (2023), 1776 Avenue of the States Lexington, Kentucky 40511, available at https://mic3.net/wp-content/uploads/2020/06/MIC3-Rules-Book_Dec2023_WEB_1-10-24.pdf. This compliance period is consistent with the period the Department establishes at proposed new N.J.A.C. 8:57-4.9(b) with respect to a minor entering, or transferring into, a facility from outside of the USA. Therefore, proposed new N.J.A.C. 8:57-4.9(c) would reflect the applicability of the compact to eligible minors, and would make them subject to the same compliance periods as in proposed new subsection (b), subject to proposed new subparagraph (c)1, which would acknowledge that subsection (c) could be preempted or superseded, pursuant to N.J.S.A. 18A:75A-13, if the MIC3 were to amend its rules to provide longer compliance periods. Proposed new N.J.A.C. 8:57-4.9(c)2 would provide communication information for the MIC3.

The Department proposes to repeal existing N.J.A.C. 8:57-4.10, Diphtheria and tetanus toxoids and pertussis vaccine, and proposes a new rule at N.J.A.C. 8:57-4.10, Exclusion of persons during actual or threatened vaccine-preventable disease outbreak. As described above, N.J.S.A. 26:1A-9.1 and 26:4-6 authorize the Commissioner to require an administrator to exclude a person who is unimmunized or under-immunized from attendance at a facility during an emergency. Proposed new N.J.A.C. 8:57-4.10(a) would implement N.J.S.A. 26:1A-9.1 and 26:4-6 by requiring an administrator, upon the direction of the Commissioner or the health officer with jurisdiction, to exclude

unimmunized, under-immunized, and provisionally admitted minors from attendance at a facility during an actual or threatened communicable disease outbreak or a public health emergency. Subsection (b) would reiterate the authority of an administrator to exclude a person from attendance, "on account of the prevalence of any communicable disease, or to prevent the spread of communicable diseases," and would indicate that the Commissioner or the local health agency would determine whether a communicable disease is "prevalent," whether exclusion of any person is necessary to prevent the spread of a communicable disease, and the period of exclusion. To facilitate the prompt implementation of proposed new N.J.A.C. 8:57-4.10(a) and (b), subsection (c) would require an administrator to maintain an up-to-date list of unimmunized, under-immunized, and provisionally admitted minors and to make the list available to the Department and/or the local health agency upon request during an actual or a suspected communicable disease outbreak, or a public health emergency. Subsection (d) would authorize an administrator to notify a parent requesting an immunization exemption on behalf of a minor, pursuant to proposed new N.J.A.C. 8:57-4.7 or -4.8, or provisional admission, pursuant to N.J.A.C. 8:57-4.9, that, if an administrator grants these requests, the minor is subject to exclusion from attendance during an actual or a suspected communicable disease outbreak, or a public health emergency.

The Department proposes to repeal existing N.J.A.C. 8:57-4.11, Poliovirus vaccine, and proposes a new rule at N.J.A.C. 8:57-4.11, Reports to be sent to the Department and local health agencies. Proposed new N.J.A.C. 8:57-4.11 would identify administrator responsibilities to report the immunization status of facility attendees into the NJIIS using the Annual Immunization Status Report at proposed new Appendix M.

Subsection (a) would require this report to be submitted to the NJIIS by December 1 of each year. Subsection (b) would indicate that the Department would notify applicable State agencies and local health agencies of facility or administrator delinquencies in compliance with this section.

The Department proposes to repeal existing N.J.A.C. 8:57-4.12, Measles virus vaccine, and a new rule at N.J.A.C. 8:57-4.12, Meningitis-Containing Vaccination Immunization Information Fact Sheet established. N.J.S.A. 26:2X-3 directs the Commissioner, in consultation with the Commissioner of Education, to "develop an educational fact sheet" that addresses, at minimum, "the causes, symptoms, and means of transmission of meningococcal meningitis; … the availability, effectiveness, and risks of the meningitis vaccine; and … where additional information concerning the disease can be obtained." N.J.S.A. 18A:40-21.2 directs the Commissioner of Education to establish requirements by which school districts are annually to disseminate "the educational fact sheet to parents or guardians of students in the sixth grade," and "make the educational fact sheet available to private schools educating students in grades [six] through 12, or any combination thereof," and encourages schools "to distribute the fact sheet to parents or guardians of students at the school." Proposed new N.J.A.C. 8:57-4.12 would establish the brochure entitled "Meningococcal Disease: Are You Protected?" as the fact sheet that the Commissioner is to promulgate, in consultation with the Commissioner of Education, pursuant to N.J.S.A. 26:2X-3, and for which the Commissioner of Education is to establish school district dissemination procedures pursuant to N.J.S.A. 18A:40-21.2.

The Department proposes to repeal existing N.J.A.C. 8:57-4.13, Rubella vaccine, and proposes a new rule, N.J.A.C. 8:57-4.13, Immunization of children at public expense authorized, which would reiterate the authority of boards of education and local boards of health to undertake immunization of minors at public expense, pursuant to N.J.S.A. 18A:40-20 and -26, and N.J.S.A. 26:4-8.1.

The Department proposes to repeal existing sections N.J.A.C. 8:57-4.14 through 4.21. As at N.J.A.C. 8:57- 4.10 through 4.13, proposed for repeal, N.J.A.C. 8:57-4.14 through 4.21 identify immunization requirements with respect to individual vaccines. These provisions would no longer be needed because N.J.A.C. 8:57-4.2, as proposed for amendment, and proposed new N.J.A.C. 8:57-4.3, would incorporate by reference, as amended and supplemented, the ACIP recommendations for vaccines as to which an administrator is to require evidence of immunization or immunity as a precondition to attendance at a facility.

The Department proposes to recodify existing N.J.A.C. 8:57-4.22, Emergency powers of the Commissioner, Department of Health and Senior Services, as new N.J.A.C. 8:57-4.14, Emergency powers of the Commissioner, and proposes amendments to require an administrator to exclude any person failing to meet existing or modified immunization requirements as set forth by the Commissioner, including persons with a medical contraindication or religious exemption, in cases of outbreak, or public health emergency. Subsection (d), as proposed for amendment, would indicate that the Commissioner can determine that New Jersey is affected by a vaccine supply shortage as referenced in the subsection.

Subchapter 5

Existing N.J.A.C. 8:57-5, Management of Tuberculosis, establishes standards addressing the management of tuberculosis in the State. The Department proposes to make technical changes throughout the chapter to correct grammar and spelling, improve readability, delete binary gender terminology, and reflect a change in the name of a Federal public health authority.

N.J.A.C. 8:57-5.3, Definitions, establishes definitions of terms the subchapter uses. The Department proposes to amend the section to add a definition of and communication information for the "TB Program" and proposes corresponding amendments throughout the chapter to delete redundant references to the TB Program's communication information.

Existing N.J.A.C. 8:57-5.5, Hospital discharge, establishes standards by which a TB patient is to be discharged from a hospital. The Department proposes to amend the section to delete (a)3ii, to remove the discharge eligibility of a person who obtains a negative nucleic acid amplification test result.

The Department proposes to amend existing N.J.A.C. 8:57-5.6, Health officer responsibilities, 5.8, Diagnostic evaluations, and 5.9, Directly Observed Therapy, to delete references to a Department publication that formerly existed but is no longer in use, the "Standards of Care for Tuberculosis Disease and Latent TB Infection."

The Department proposes to amend existing N.J.A.C. 8:57-5-16, Annual report, to make a technical change to update the website where the TB program's annual reporting describing trends in prevalence and incidence of TB in New Jersey is located, and to delete an unnecessary reference to the TB Program Manager.

Subchapter 6

Existing N.J.A.C. 8:57-6, Higher Education Immunization, establishes standards applicable to certain institutions of higher education (IHEs), with respect to obtaining and maintaining records of immunization or immunity of IHEs' admitted and enrolled attendees. The Department proposes repeals and new rules at N.J.A.C. 8:57-6.1 through -6.15.

Proposed new N.J.A.C. 8:57-6.1, Scope, would establish the scope of the chapter as applicable to "institutions of higher education" as specified in the proposed definition of that term at N.J.A.C. 8:57-1.3, proposed for recodification as new N.J.A.C. 8:57-1.2. Proposed new subsection (b) would indicate that the subchapter does not limit a private entity's ability to exclude from enrollment persons who do not have (1) immunizations that the subchapter requires or (2) any additional immunizations that the subchapter does not require but that are consistent with ACIP recommendations.

Proposed new N.J.A.C. 8:57-6.2, Designation of IHE institutional liaison, at subsection (a), would establish a procedure by which an IHE is to designate an institutional liaison, and to notify the Department of any change in this designation, by use of the Institutional Liaison Designation form at proposed new Appendix P. Subsection (b) would establish that the duties and access of the institutional liaison are to: (1) serve as the IHE's representative to and primary point of communication with the Department, specifically the VPDP, with respect to the Department's oversight of the IHE's compliance with N.J.A.C. 8:57-6 and other applicable laws governing immunization of a graduate or undergraduate student (hereinafter "collegian") ; (2) have access to immunization records that the subchapter requires an IHE to maintain; and (3)

administer and implement any corrective action that the Department requires the IHE to undertake to maintain the IHE's compliance with this subchapter. Proposed new subsection (c) would require the highest-ranking official within an IHE to notify the Department of any changes to the identity or communication information of an institutional liaison through submission of a new Institutional Liaison Designation form.

N.J.S.A. 18A:61D-1 requires an IHE in New Jersey, in accordance with rules that the Department is to promulgate, (1) to condition admission or continued enrollment of a collegian who is 30 years old and under, and enrolled full-time or part-time in a program or course of study leading to an academic degree, upon a collegian's submission to the IHE of a record documenting the collegian's receipt of required immunizations against vaccine-preventable diseases, or evidence of immunity from these diseases, and (2) to maintain these records.

Proposed new N.J.A.C. 8:57-6.3, IHE to require certain collegians to submit a record of compliance with N.J.A.C. 8:57-4 pursuant to N.J.S.A. 18A:61D-1, would implement this requirement by requiring an IHE to condition a collegian's enrollment on the collegian's submission of evidence of immunization compliant with N.J.A.C. 8:57-6.4 for the diseases against which N.J.A.C. 8:57-4 requires immunization, including Catch-up Schedules then-applicable to that collegian, and to exclude a collegian who is unable to provide evidence of immunization. A typical collegian would be required to provide evidence of immunization or immunity against measles, mumps, and rubella, subject to N.J.A.C. 8:57-6.5, 6.6, 6.7, and 6.8, and 6.12, described below. For a collegian who provides insufficient evidence of immunization, subsection (b) would condition the collegian's admission and/or continued admission to the IHE on the collegian obtaining

the required immunizations and thereafter submitting the required documentation consistent with (a) above. Subsection (c) would direct an IHE to not admit or retain any student who does not meet the immunization requirements in accordance with the section.

Proposed new N.J.A.C. 8:57-6.4, Evidence of immunization, would establish the forms of evidence of immunization that an IHE would be authorized to accept to comply with N.J.A.C. 8:57-6.3, and associated recordkeeping requirements, and would require an IHE that does not receive evidence that is satisfactory to the institutional liaison or the VPDP of a collegian's receipt of a required immunization to require the collegian to obtain missing, and/or repeat invalid, doses and to submit evidence of immunization to the IHE. Subsection (a) would require an IHE to accept and maintain documentation, listed in (b) below, as evidence of a collegian's immunization from diseases identified in N.J.A.C. 8:57-6.4, -6.10 and/or -6.11, and identify the required elements to satisfy these requirements. Subsection (b) would identify the following as acceptable forms of evidence: (1) an official school record, (2) a record from a government health authority of the USA, (3) a record signed by one of the indicated health care professionals, (4) an official record from NJIIS or the Docket® application or website, or a successor application, and (5) a record signed by a foreign health service provider or government agency, provided any records in a language other than English are accompanied with a certified translation. Subsection (c) would establish the criteria an IHE is to use in evaluating evidence submitted by a collegian. Subsection (d) would require a collegian who is unable to present satisfactory evidence to obtain missing doses and/or repeat doses and submit evidence thereof within 10 days. Subsection (e) would require an

IHE to make reasonable efforts to verify any document submitted by a collegian if the IHE or the VPDP has reason to doubt the document's authenticity.

Proposed new N.J.A.C. 8:57-6.5, Evidence of immunity, at subsection (a), would authorize an IHE to accept evidence of a laboratory serologic test result consistent with ACIP recommendations as indicative of a collegian's immunity to, or ongoing illness with, a vaccine-preventable disease, in place of requiring the collegian to submit evidence of the collegian's receipt of required immunizations for that disease. Subsection (b) would identify the forms of evidence of a collegian's immunity that an IHE would be authorized to accept. Subsection (c) would direct an IHE to make reasonable efforts to verify the authenticity and/or content of any document submitted pursuant to this subsection if the IHE or VPDP has reason to doubt the document's authenticity or content.

Proposed new N.J.A.C. 8:57-6.6, Provisional admission and/or continued enrollment, would establish standards for provisional admission of a collegian who would otherwise be excluded from attendance at an IHE due to the collegian's inability to present required evidence of immunization against or immunity to a vaccine-preventable disease. Subsection (a) would establish conditions under which an IHE is to admit and/or continue the enrollment of a collegian who is unable to present evidence of a required immunization against or immunity to a vaccine-preventable disease, that is, the collegian must have received at least one dose of the missing immunization, is no later than 14 days behind an applicable Catch-up Schedule in receiving any remaining required doses, and presents evidence of timely immunization or immunity. Subsection (b) would establish conditions under which an IHE is to admit and/or

continue the enrollment of a collegian from outside the USA, for no longer than 30 days, if, during that period, the collegian obtains, and provides to the institution, evidence of required immunizations or immunity, and maintains compliance with an applicable Catch-up Schedule.

Proposed new N.J.A.C. 8:57-6.7, Medical exemption from compliance with N.J.A.C. 8:57-6.3, -6.10, and/or -6.11 pursuant to N.J.S.A. 18A:61D-10, and 18A:62-15.2, would establish, at subsection (a), an exemption from a collegian's obligation to present evidence of a required immunization if compliance would be medically contraindicated or present a precaution. Subsection (b) would require a collegian seeking to use the exemption to submit a Request for Medical Exemption from Mandatory Immunization at proposed new Appendix L, or the information requested therein in writing, executed by one of the indicated health care professionals. Subsection (c) would establish the process by which an IHE is to review, retain, and condition admission based on the submission of the form or document submitted pursuant to subsection (b). Subsection (d) would identify the ability of an IHE to consult with the VPDP to obtain assistance in reviewing statements submitted pursuant to the section.

N.J.S.A. 18A:61D-3 directs an IHE to exempt a collegian from compliance with N.J.S.A. 18A:61D-1 if the collegian submits "a written statement that immunization conflicts with [the collegian's] religious beliefs." Because N.J.S.A. 18A:61D-1 requires an IHE to confirm a collegian's receipt of primary childhood immunizations, the religious exemption available at N.J.S.A. 26:1A-9.1, which requires submission of a written statement "that the proposed immunization interferes with the free exercise of the

pupil's religious rights," is also available to a collegian for those primary childhood immunizations.

Proposed new N.J.A.C. 8:57-6.8, Religious exemption from compliance with N.J.A.C. 8:57-6.3 pursuant to N.J.S.A. 18A:61D-3 and 26:1A-9.1, at subsection (a), would implement N.J.S.A. 18A:61D-3 and 26:1A-9.1 by establishing the procedure by which an IHE is to exempt a collegian from compliance with N.J.A.C. 8:57-6.3 on religious grounds, and the associated recordkeeping requirements. Subsection (b) would require a collegian to comply with N.J.A.C. 8:57-6.3 for immunizations to which they do not assert a religious conflict or interference. Subsection (c) would specify that an IHE is not to grant an exemption solely on a moral or philosophical objection. Subsection (d) would require an IHE to retain any statement submitted pursuant to the subchapter. Subsection (e) would indicate that an IHE is not to require a collegian to annually resubmit an exemption request for which the IHE has a record of an approved exemption. Subsections (f) and (g) would require an IHE to deem nullified a collegian's religious exemption of record if the collegian obtains an immunization in contravention of the assertion contained in the collegian's written statement, and to require a collegian to submit a new request for a religious exemption if the collegian seeks to reinstate the exemption with respect to subsequent doses.

Proposed new N.J.A.C. 8:57-6.9, Exclusion of collegian due to vaccine-preventable diseases pursuant to N.J.S.A. 18A:62-15.2, and N.J.S.A. 26:1A-9.1 and N.J.S.A. 26:4-6, at subsection (a), would require an IHE, in the event of a confirmed or suspected preventable disease outbreak, to exclude an unimmunized, under-immunized, and provisionally admitted collegian who has otherwise been admitted to

the IHE. Subsection (b) would state the authority by which a school can prohibit attendance in accordance with (a) above. Subsection (c) would require the local health agency or the Department to provide direction to the institutional liaison related to communicable disease prevalence, necessity of prohibition of attendance, categories of excluded persons based on immunization status, and the period during which these persons are to be prohibited from attendance. Subsection (d) would require an institutional liaison to maintain a record of each collegian admitted pursuant to N.J.A.C. 8:57-6.6, -6.7, -6.8, and -6.12, and make that list available to the Department and/or the local health agency upon request.

N.J.S.A. 18A:61D-9 directs an IHE to exclude from continued attendance a collegian who does not present evidence of immunization against hepatitis B within nine months of attendance. This requirement applies to all collegians, regardless of age, who register for 12 or more credit hours of course study per semester or term and enroll in a program of the IHE leading to an academic degree. Proposed new N.J.A.C. 8:57-6.10, would require the IHE to require certain collegians to submit a record of compliance with N.J.S.A. 18A:61D-9 regarding immunization against or immunity to hepatitis B, would implement N.J.S.A. 18A:61D-9 by directing an IHE to require a collegian to whom the section applies to submit evidence of immunization against, or immunity to, hepatitis B that is compliant with N.J.A.C. 8:57-6.4 or -6.5.

Some collegians to whom N.J.S.A. 18A:61D-9 applies concurrently would be required to submit evidence of hepatitis B immunization or immunity pursuant to 18A:61D-1, as implemented by proposed new N.J.A.C. 8:57-6.3. For example, see N.J.S.A. 18A:40-21.1, described above in the discussion of Subchapter 4, which

requires high school students to receive the hepatitis B vaccination. Proposed new N.J.A.C. 8:57-6.10(c) would specify the section would not extend the time within which an IHE is to obtain evidence of hepatitis B immunization or immunity from a collegian who is subject to N.J.A.C. 8:57-6.3. Proposed new N.J.A.C. 8:57-6.10(d) would indicate that an IHE that obtains evidence of hepatitis B immunization or immunity from a collegian to comply with proposed new N.J.A.C. 8:57-6.4 or -6.5 is not to require a collegian to submit redundant evidence to comply with proposed new N.J.A.C. 8:57-6.10. N.J.S.A. 18A:61D-9 establishes a compliance grace period, that is, within nine months of attendance. Proposed new subsection (e) would direct an IHE to not admit or retain a collegian who is not compliant. Subsection (f) would reiterate that provisional admission pursuant to N.J.A.C. 8:57-6.6 is inapplicable to an IHE's compliance with N.J.A.C. 8:57-6.10.

N.J.S.A. 18A:62-15.1 directs an IHE to exclude from continued attendance a collegian who does not present evidence of having received meningococcal-containing vaccine. This requirement applies to all collegians, regardless of age, as a condition of attendance. Proposed new N.J.A.C. 8:57-6.11, IHEs to require collegian to submit record of compliance with N.J.S.A. 18A:62-15.1, would implement N.J.S.A. 18A:62-15.1 by directing an IHE to require a collegian to whom the section applies to submit evidence of immunization compliant with N.J.A.C. 8:57-6.4. Subsection (a) would indicate that the requirement would apply to a collegian for whom applicable ACIP recommendations to receive the vaccine exist. Subsection (b) would state that the obligation to receive meningococcal-containing vaccine applies to a collegian who

enrolls in an IHE, regardless of age. Subsection (c) would direct an IHE not to admit or retain a collegian who is not in compliance with the section.

N.J.S.A. 18A:61D-10 and 18A:62-15.2 authorize IHEs to exempt a collegian on religious grounds from compliance with the hepatitis B immunization required by N.J.S.A. 18A:61D-9 (to be implemented by proposed new N.J.A.C. 8:57-6.10) and the meningococcal-containing immunization required by N.J.S.A. 18A:62-15.1 requires (to be implemented by proposed new N.J.A.C. 8:57-6.11). N.J.S.A. 18A:61D-10 and 18A:62-15.2 specify the required content of the written statement that a collegian is to submit to an IHE in support of a request for exemption from these immunizations, which is different from the required content of the written statement that a collegian must submit in support of a religious exemption from compliance with N.J.S.A. 18A:61D-1, pursuant to N.J.S.A. 18A:61D-3. N.J.S.A. 18A:61D-10 and 18A:62-15.2 require a collegian seeking an exemption from compliance with N.J.S.A. 18A:61D-9 or 18A:62-15.1 on religious grounds to submit a written statement to the institution "explaining how the administration of the vaccine conflicts with the bona fide religious tenets or practices of the student, or the parent or guardian, as appropriate."

Proposed new N.J.A.C. 8:57-6.12, Religious exemption from compliance with N.J.A.C. 8:57-6.10 and -6.11 pursuant to N.J.S.A. 18A:61D-10 and 18A:62-15.2, would implement N.J.S.A. 18A:61D-10 and 18A:62-15.2 by establishing procedures by which an institution is to exempt a collegian from compliance with proposed new N.J.A.C. 8:57-6.10 and -6.11 on religious grounds, and associated recordkeeping requirements. Subsection (a) would require a collegian to submit a written statement as to the basis of the religious exemption . Subsection (b) would prohibit an IHE from granting an

exemption on the sole basis of a general philosophical or moral objection. In deference to a religious-affiliated IHE's authority and expertise to determine whether the religion with which the IHE affiliates recognizes the receipt of a specific vaccine as conflicting or interfering with that religion, subsection (c) would reflect a religious-affiliated IHE's authority to withhold or grant a request for religious exemption under this section without challenge by a secular health authority. Subsection (d) would require an IHE to retain any statement submitted pursuant to subsection (a) in accordance with the recordkeeping requirements at N.J.A.C. 8:57-6.13. Subsection (e) would require an IHE to not require a collegian who obtains an exemption pursuant to the section to reapply annually for the exemption.

N.J.S.A. 18A:61D-1 requires an IHE to maintain collegians' immunization records "on file in such form and manner as prescribed by the [Department]." N.J.S.A. 18A:61D-9 and 18A:62-15.1 direct the Department to promulgate rules to implement the immunization requirements contained therein. Proposed new N.J.A.C. 8:57-6.13, IHE's obligations with respect to collegians' immunization records pursuant to N.J.S.A. 18A:61D-1, would establish the obligations of an IHE with respect to collegians' immunization records. Subsection (a) would require an IHE to segregate immunization records from collegians' other confidential records without compromising the confidentiality of the collegian's other educational or medical records; make immunization records available on request to the Department and local health agencies with jurisdiction; and ensure that each record contains the required content. Subsection (b) would require an IHE to establish policies and procedures, consistent with its handling of other record requests, to provide collegians their immunization transcripts.

Subsection (c) would require an IHE to address a collegian's request for a copy or transmittal of the collegian's immunization transcript consistent with the policies and procedures that the IHE establishes pursuant to subsection (b).

N.J.S.A 18:61D-9 directs the Commissioner to establish rules requiring an IHE to offer hepatitis B vaccines through its student health service or a contractual agreement with a community health care provider. N.J.S.A. 18A:62-15.1 directs the same in reference to the meningococcal-containing vaccination. Proposed new N.J.A.C. 8:57-6.14, IHEs to offer hepatitis B and meningococcal-containing vaccine pursuant to N.J.S.A. 18:61D-9 and 18A:62-15.1, would implement these statutes by requiring an IHE to make the hepatitis B and meningococcal-containing vaccines available to collegians through either the IHE's student health services program or through a contractual agreement with a health care professional in the community.

N.J.S.A. 18A:61D-7(a), directs the Commissioner to establish rules by which "each four-year public or private institution of higher education in this State" is to "provide information about meningitis," and the meningococcal-containing vaccination requirement, "to all prospective students prior to their matriculation, and include with that information notice of the availability and benefits of a meningococcal vaccination." N.J.S.A. 18A:61D-7, at subsection b, directs the Commissioner to establish rules requiring these IHEs to "develop procedures for facilitating, receiving and recording student responses to the information provided pursuant to subsection a. of this section," including compliance with meningococcal-containing vaccination requirements "and the decision of any student who is exempted from that requirement to receive the vaccination."

Proposed new N.J.A.C. 8:57-6.15, Certain IHEs to offer information about meningitis and meningococcal-containing vaccine immunization requirement pursuant to N.J.S.A. 18A:61D-7, would implement this statute by requiring an IHE to disseminate the Department brochure entitled “Meningococcal Disease: Are You Protected?” to all prospective collegians, regardless of age, prior to their matriculation, and to develop procedures to obtain and record each prospective collegian’s response to the brochure, assess prospective collegians’ compliance with meningococcal-containing vaccination requirements, and memorialize whether prospective students who are exempt from compliance with meningococcal-containing vaccination requirements nonetheless decide to receive the meningococcal-containing vaccine following receipt of the brochure.

The Department proposes to repeal existing N.J.A.C. 8:57-6.16, Institutional records required, as it would be redundant of other provisions of the proposed new rules that establish recordkeeping requirements.

Existing N.J.A.C. 8:57-6.17, Reports to be submitted to the Department, identifies reports that an IHE is required to submit to the Department. The Department proposes to recodify existing N.J.A.C. 8:57-6.17, as new 6.16, Reports to be submitted to the Department, and amend subsection (a) to establish a submission deadline of December 1 for each year’s Annual College Immunization Status Report, which the Department proposes to recodify from existing Subchapter 6 Appendix as new Appendix Q. The Department proposes to amend the form to add fields relating to the meningococcal-containing and hepatitis B vaccines, and the delivery method of these vaccines.

The Department proposes to repeal N.J.A.C. 8:57-6.18, -6.19, -6.20, and -6.21, as these sections would be redundant of other provisions of the proposed new rules in Subchapter 6.

Social Impact

The proposed amendments throughout the chapter to reorganize sections and improve style would make the chapter more user-friendly.

N.J.A.C. 8:57-1

The proposed amendments, recodifications, repeals, and new rules at N.J.A.C. 8:57-1 would have a beneficial social impact on the regulated public. The reorganization of this subchapter would provide a more user-friendly framework for the N.J.A.C. 8:57, thus making it easier to understand by the regulated public.

The proposed repeal and new rule at N.J.S.A. 8:57-1.1 would guide users by specifying the legal standards and topics the chapter would address and implement.

The proposed amendment of existing N.J.A.C. 8:57-1.3, to be recodified as new N.J.A.C. 8:57-1.2, would ensure that the regulated public understands the meaning of terms the chapter uses.

Proposed new N.J.A.C. 8:57-1.4, to be recodified from existing -1.15, and the proposed amendment of existing N.J.A.C. 8:57-4.24, to be recodified as new N.J.A.C. 8:57-1.5, would ensure that the regulated public is cognizant of available sanctions for noncompliance with the chapter.

Proposed new N.J.A.C. 8:57-1.6 would facilitate unimpeded access of Department staff to premises and things in the implementation of the chapter.

The proposed amendment of existing N.J.A.C. 8:57-1.14, to be recodified as new N.J.A.C. 8:57-1.7, would identify confidentiality protections applicable to records and information relating to the matters the chapter addresses that the Department and local public health authorities may generate or hold, thereby enhancing public confidence in the security of their personal health information.

N.J.A.C. 8:57-2

The proposed amendments, recodifications, repeals, and new rules at N.J.A.C. 8:57-2 would have a beneficial social impact on the regulated public. Communicable diseases continue to be a leading cause of preventable morbidity and mortality. Reporting of communicable diseases to public health officials facilitates early intervention and implementation of control measures to prevent disease spread. Rapid response to prevent the spread of communicable diseases improves population health, avoids worker and student absenteeism due to illness, and prevents sequelae associated with communicable diseases. By updating this subchapter, the public health system would be able more efficiently to prepare for and respond to public health issues and thereby protect public health.

The proposed amendment of existing N.J.A.C. 8:57-1.4, to be recodified as new N.J.A.C. 8:57-2.2, would ensure that entities with reporting obligations are aware of the processes and requirements for reporting cases.

The proposed amendment of existing N.J.A.C. 8:57-1.5, to be recodified as new N.J.A.C. 8:57-2.3, reclassifying the reporting deadlines for certain diagnoses and changing the types of cases that are reportable, would reflect changes in the relative urgency with which public health authorities must respond to these reports, based on

changes to available treatments and/or enhanced understanding of certain bioterrorism concerns.

The proposed amendment of existing N.J.A.C. 8:57-1.6, to be recodified as new N.J.A.C. 8:57-2.4, would restate and simplify reporting obligations and processes to ensure they are understandable to those who must report cases.

Proposed new N.J.A.C. 8:57-2.5 would enable clinical laboratories with reporting obligations to adhere to national standards for electronic reporting, thereby enhancing or maintaining their eligibility for Federal financial incentives associated with use of electronic health records, and standardizing reporting by clinical laboratories that participate in multijurisdictional result reporting.

Like proposed new N.J.A.C. 8:57-2.4, the proposed amendment of existing N.J.A.C. 8:57-1.7, to be recodified as new N.J.A.C. 8:57-2.6, reclassifying the reporting deadlines for laboratory results indicative of the presence of certain organisms that cause communicable diseases, infections, or conditions, and outbreaks thereof, and modifying the types of results that are reportable with respect to certain organisms, would reflect changes in the relative urgency with which public health authorities must respond to those reports, based on changes to available treatments and/or enhanced understanding of certain organisms, diseases, and bioterrorism concerns, and thereby promote more efficient and effective use of available public health authority resources. The proposed amendment of existing N.J.A.C. 8:57-1.8, to be recodified as new N.J.A.C. 8:57 2.7, revising the reporting obligations and procedures applicable to veterinarians, would reflect changes in the relative urgency of public health authority

response to veterinary and zoonotic diseases, and thereby promote more efficient and effective use of available public health authority resources.

The proposed amendment of existing N.J.A.C. 8:57-1.9, to be recodified as new N.J.A.C. 8:57-2.8, would ensure that health officers who receive and make reports of cases and laboratory results process these in the manner, and to the public health authority, that is most appropriate under the circumstances, depending on the nature of the disease or organism reported and applicable jurisdictional factors.

The proposed amendment of existing N.J.A.C. 8:57-1.10, to be recodified as new N.J.A.C. 8:57-2.9, identifying, and requiring health officers' adherence to, specified best practices for investigating confirmed and suspected cases, infections, and outbreaks, specifying the minimum content of investigation reports, and requiring health officers to submit status reports pending their issuance of final reports and closing investigations, would ensure that the Department has uniform, timely, and comprehensive information to determine and implement Statewide responsive measures, and would incentivize health officers to conclude investigations rather than indefinitely maintaining them in pending status.

The proposed amendment of existing N.J.A.C. 8:57-1.11, to be recodified as new N.J.A.C. 8:57-2.10, and the proposed amendments to the Model Ordinance for Quarantine and Isolation, would ensure that local governing bodies have appropriate standards in place to address isolation and quarantine of persons, as well as pet birds and other domestic companion animals, as necessary to protect public health.

The proposed amendment of existing N.J.A.C. 8:57-1.13, to be recodified as new N.J.A.C. 8:57-2.11, would protect food establishment, drug establishment, and cosmetic

establishment workers and patrons from exposure to communicable diseases that are transmissible through food, drugs, and cosmetics, would implement N.J.S.A. 24:15-10 more fully by including drugs and cosmetics workers within the scope of the rule, and would ensure that employers exclude workers in consultation with the Department or the local health authority, thereby discouraging arbitrary exclusion of workers.

Proposed new N.J.A.C. 8:57-2.12 and 2.13, which would establish reporting requirements for schools and nursing homes, would ensure that the Department has routine information to respond to a public health concern affecting these facilities' vulnerable populations.

N.J.A.C. 8:57-3

The proposed amendments, recodifications, repeals, and new rules at N.J.A.C. 8:57-3 would have a beneficial social impact on the regulated public by:

Reestablishing, simplifying, and updating the norms and procedures for enrollment in and use of the NJIIS to make the NJIIS more user friendly, and thereby ease NJIIS user participation;

Establishing requirements for NJIIS participation and enrollment by eligible entities, thereby fostering a more robust NJIIS userbase;

Restating NJIIS user access levels to ensure that each NJIIS user has access to the minimum necessary NJIIS information that is appropriate to the NJIIS user's role, thereby protecting NJIIS information confidentiality;

Establishing NJIIS training requirements to ensure accurate and proper use and data collection;

Alerting NJIIS sites and NJIIS users of their expected conduct in NJIIS interactions, including adherence to security and confidentiality standards;

Establishing secure procedures for viewing, sharing, and correcting information in NJIIS;

Facilitating Department oversight actions and intervention to address system threats;

Protecting the confidentiality and ensuring the accuracy of NJIIS content;

Facilitating and identifying procedures by which an individual can ensure that the NJIIS contains the individual's accurate immunization record through the correction request process, obtain access to the individual's NJIIS record, and deactivate the individual's NJIIS record by withdrawal;

Identifying procedures by which the NJIIS can engage with immunization registries in other jurisdictions to collect and share data securely and in accordance with updated and nationally recognized data exchange policies and procedures, thereby promoting the accuracy and robustness of the information in the NJIIS and enabling an enrolled person who relocates to another jurisdiction to have their NJIIS records transferred to the new jurisdiction.

N.J.A.C. 8:57-4

Vaccine-preventable diseases remain a threat to school-aged and preschool-aged children. Prevention of individual cases and outbreaks of vaccine-preventable diseases require high immunization levels among school-aged and preschool-aged children. These prevention efforts in turn help individuals and communities avoid the

physical sequelae, morbidities, and mortalities that these diseases can cause, and curtail the associated high social costs that otherwise would burden children, their families, and the community.

The proposed amendments, recodifications, repeals, and new rules at N.J.A.C. 8:57-4 would have a beneficial social impact on the regulated public by ensuring that health care professionals adhere to nationally recognized best practices and immunization schedules in administering vaccines to the people of New Jersey, thereby promoting their health and safety and protecting them and others from contracting vaccine-preventable diseases; ensuring that each facility administrator obtains appropriate evidence of each minor's immunization or immunity to vaccine-preventable diseases, thereby protecting each minor and others admitted to the facility, including attendees who are unable to receive vaccinations due to medical contraindications and who must rely on "herd immunity" to avoid exposure to diseases; and enabling minors to avoid unnecessary or duplicative vaccination through the submission of laboratory evidence of protective immunity from vaccine-preventable diseases.

N.J.A.C. 8:57-5

The proposed amendment at N.J.A.C. 8:57-5.5 deleting reference to the nucleic acid amplification test would have a beneficial social impact because the test is inadequate to confirm that a person's TB disease is not transmissible and could unnecessarily prolong a person's hospital stay.

Except as described above, the Department does not anticipate that the proposed amendments at N.J.A.C. 8:57-5 would have a social impact because the proposed amendments would make only technical changes to the subchapter.

N.J.A.C. 8:57-6

The proposed amendments, recodifications, repeals, and new rules at N.J.A.C. 8:57-1 would have a beneficial social impact on the regulated public by facilitating Department interaction and coordination with each IHE to ensure that each IHE provides a safe environment that is free from vaccine-preventable diseases, thereby reducing the risk of avoidable illnesses and outbreaks on campuses; allowing IHEs to use campus spaces at which enrolled collegians can congregate without risking the spread of disease, thereby ensuring that IHEs can continue to offer and maintain collegians' social and educational opportunities; promoting high overall immunization levels at IHE campuses by the establishment of limited provisional admission periods during which collegians can obtain missing vaccinations at IHE health centers, if necessary, upon their arrival at campus, and thereby enabling these collegians to avoid exclusion from attendance; and promoting collegian awareness and education about the risk of meningitis and the availability of the meningococcal-containing vaccine to protect them from this disease.

Economic Impact

N.J.A.C. 8:57-1

The proposed amendments, recodifications, repeals, and new rules at N.J.A.C. 8:57-1 would have a beneficial economic impact on the regulated public. Prevention and/or limitation of the spread of communicable disease is a cost-efficient use of financial resources to support public health. By promulgating legal standards, explaining the definitions used within the chapter, and providing information about

sanctions and confidentiality, this chapter will allow the rules of this chapter to be clear and easily implemented by the public and other health institutions. Consequently, this will have a positive effect on the overall public health, which will avoid healthcare costs and reduced absenteeism resulting from the sequelae, morbidities, and mortalities associated with contraction of vaccine-preventable diseases.

N.J.A.C. 8:57-2

The proposed amendments, recodifications, repeals, and new rules at N.J.A.C. 8:57-1 would have a beneficial economic impact on the regulated public. Prevention and/or limitation of the spread of communicable disease continues to be a cost-efficient use of financial resources that are available to support public health, because reporting facilitates cost-saving interventions that protect and improve population health, avoid worker, student, and associated parent absenteeism due to illness, and prevent incurring health care costs to treat communicable diseases.

The proposed amendments and new rules at N.J.A.C. 8:57-2 and 3 would support these efforts. Entities with reporting obligations are likely to have the necessary infrastructure in place to submit required reports. They would continue to incur administrative expenses associated with reporting cases and laboratory results, such as staff time, and information technology acquisition and maintenance. The types of entities upon which the chapter would impose reporting obligations would not change, making it unlikely that the existing economic burden of compliance would change. Compliance with electronic laboratory reporting obligations may facilitate clinical

laboratories' eligibility for Federal financial incentives associated with electronic health recordkeeping.

N.J.A.C. 8:57-3

Entities with reporting obligations that the proposed amendments, recodifications, repeals, and new rules at N.J.A.C. 8:57-3 would establish would remain the same as under the existing rules. NJIIS sites and NJIIS users would continue to incur administrative costs associated with staff retention to comply with immunization reporting requirements and the time needed for NJIIS users to receive required NJIIS training.

N.J.A.C. 8:57-4

The proposed amendments, recodifications, repeals, and new rules at N.J.A.C. 8:57-4 would require each facility to incur administrative and material costs associated with the collection, review, and retention of each student's submissions of evidence of immunization against or immunity to vaccine-preventable diseases and/or records supporting exemptions due to medical contraindications and religious objections, and reporting facility immunization status reports to the VPDP.

At the same time, an administrator's enforcement of Subchapter 4 would result in cost savings to a facility by promoting a high facility immunization level, thereby avoiding costs associated with staff and student absenteeism due to illness.

N.J.A.C. 8:57-5

The proposed amendment at N.J.A.C. 8:57-5.5 could have a beneficial economic impact because it would avoid unnecessarily prolonging a patient's hospital stay to await the result of a nucleic acid amplification test, which is inadequate to confirm whether a patient has transmissible TB, thereby avoiding the costs associated with an unnecessarily prolonged stay and the cost of an unnecessary laboratory test.

Except as described above, the Department does not anticipate that the proposed amendments at Subchapter 5 would have an economic impact because they are primarily technical in nature.

N.J.A.C. 8:57-6

The proposed amendments, recodifications, repeals, and new rules at N.J.A.C. 8:57-6 would continue to require IHEs to incur costs associated with the retention and maintenance of information technology equipment, the retention and identification of an Institutional Liaison, and other staffing and administrative expenses associated with the collection, review, and retention of each collegian's immunization or immunity record and/or exemption request due to medical contraindication or religious objection, and reporting immunization census information to the VPDP.

At the same time, Subchapter 6 would promote a high immunization level at IHE campuses, which would help IHEs avoid costs associated with staff and collegian absenteeism due to illness. Avoidance of preventable illnesses in turn could help lower costs that IHEs would otherwise incur at IHE health centers to provide health care services to collegians who contract vaccine-preventable illnesses. Collegians and their families would also realize cost savings that they might otherwise incur, due to illness

with vaccine-preventable disease, associated with obtaining health care, absenteeism from classes and employment, and the sequelae, morbidity, and mortality resulting from vaccine-preventable disease.

Federal Standards Statements

In Subchapter 1, within the definitions at N.J.A.C. 8:57-1.2, as proposed for recodification with amendment from N.J.A.C. 8:57-1.3, the Department elects to incorporate by reference Federal guidance documents and publications and Federally endorsed or supported publications that establish best practices and procedures to which Subchapters 2 and 5 refer with respect to the identification, electronic reporting, epidemiologic investigation, and response to communicable diseases, infections, and conditions, outbreaks thereof, and laboratory test results relating to the identification of the causative organisms thereof. These include the CDC *Laboratory Recommendations for Syphilis Testing*, the FDA *Food Code*, the CDC *Notifiable Condition List*, the CLSI *M100™ Performance Standards for Antimicrobial Susceptibility Testing*, the United States Department of Human Services *Systematized Nomenclature of Medicine—Clinical Terms (SNOMED-CT) United States (US) Edition*, and the CDC, *Surveillance Case Definitions for Current and Historical Conditions.* No applicable Federal standard requires the Department to incorporate by reference these guidance documents and recommended standards.

In Subchapter 1, the Department further elects to incorporate by reference Federal publications and Federally supported or endorsed publications, to which Subchapters 3, 4, and 6 refer. These publications establish best practices and

procedures, and identify immunization types, schedules, laboratory serology testing, and contraindication and precaution recommendations, for children and adults. These include the several publications that the chapter collectively refers to as the ACIP recommendations.

Section 222 of the Public Health Service Act (42 U.S.C. §2l7a), as amended, established the ACIP. The ACIP has statutory roles under subsections 1928(c)(2)(B)(i) and 1928(e) of the Social Security Act (42 U.S.C. § 1396s(c)(2)(B)(i) and 1396s(e)) and subsection 2713(a)(2) of the Public Health Service Act (42 U.S.C. § 300gg-13(a)(2)).

The ACIP provides advice and guidance to the Director of the CDC regarding use of vaccines and related agents for effective control of vaccine-preventable diseases in the civilian population of the United States. The ACIP recommendations include schedules governing appropriate doses and dosing intervals, guidance on contraindications and precautions for use of vaccines and related agents, and information on recognized adverse events. The ACIP periodically reviews and, as appropriate, revises its recommendations. The CDC Director reviews and, if the Director determines to adopt them, publishes the ACIP recommendations as official CDC/HHS recommendations in the Morbidity and Mortality Weekly Report (MMWR). The Patient Protection and Affordable Care Act, Section 2713 of the Public Health Service Act, as amended, requires health plans subject thereto to cover the cost of immunizations that the ACIP recommends, without copayment or cost-sharing, if the CDC Director adopts the ACIP recommendations.

The ACIP recommendations (including the vaccines, doses, and dosing interval schedules, and the precautions and contraindications) serve as the list of vaccines for

administration to children and adolescents who are eligible to receive vaccines through the Vaccines For Children (VFC) program established at section 1928 of the Social Security Act. The VFC program is a Federally funded program that provides vaccines at no cost to children who might not otherwise be vaccinated because of inability to pay. The Secretary, and, as delegated, the CDC Director, use the ACIP recommendations in the purchase, delivery, and administration of pediatric vaccines in the VFC program.

The Department is the VFC program coordinator in New Jersey. N.J.A.C. 8:57 does not implement the VFC program; however, in administering the VFC program, the Department requires VFC providers (such as pediatricians and Federally Qualified Health Centers) to administer VFC program vaccines to eligible children in accordance with the ACIP recommendations.

As described in the Summary, N.J.A.C. 8:57-1.2 would incorporate by reference the ACIP recommendations, as amended and supplemented. No applicable Federal standard requires the Department to incorporate by reference the ACIP recommendations. N.J.S.A. 26:2-137.1 requires the Department to identify required and recommended immunizations in consideration of the ACIP recommendations. The proposed amendments, repeals, recodifications, and new rules at Subchapters 4 and 6 would require an administrator to require evidence of immunization or immunity as a condition of one's admission to and continued enrollment at a child care center, school, or IHE, in adherence to the ACIP recommendations for dose timing and intervals, laboratory serology testing, contraindications, and precautions. with respect to the vaccinations that the Department identifies as required. An administrator's adherence

to the ACIP recommendations would be subject to the exceptions at N.J.A.C. 8:57-4.3 and the provisional admission schedules at N.J.A.C. 8:57-4.9 and 6.6.

In Subchapter 1, the Department also elects to incorporate by reference nationally and internationally accepted information technology standards and coding languages that the Federal government publishes, supports, or accepts as authoritative, to which Subchapters 2 and 3 refer. These standards facilitate electronic reporting of communicable diseases, infections, and conditions, occurrences of outbreaks thereof, and laboratory test results relating to the identification of the causative organisms thereof, to the CDRSS, and immunizations and related information to the NJIIS. These include the *HL7 Implementation Guide*, the *Healthcare Effectiveness Data and Information Set*®, the *Logical Observation Identifiers Names and Codes*®. In addition, at N.J.A.C. 8:57-3.15(c), as proposed for recodification with amendment from -3.19, the Department identifies its election to adhere to and comply with the American Immunization Registry Association *Public Health Immunization Information System Interjurisdictional Memorandum of Understanding*, which is a cooperative agreement that facilitates secure interjurisdictional data-sharing among immunization information systems.

These Federally issued, supported, or endorsed standards facilitate interconnectivity and interoperability among data systems and enable the Department to collect and share data with State partners and governmental public health authorities in other jurisdictions, such as other states' communicable disease reporting systems and immunization information systems, and the CDC. The Department's election to incorporate by reference and, in some cases, either recommend or require the

regulated community to adhere to, the types of standards described above, enables the State to participate in Federal grant funding opportunities that require system interconnectivity and interoperability sufficient for the Department to engage in electronic public health data sharing with the United States Department of Health and Human Services and public health authorities within the State and in other regions, states, and jurisdictions. In addition, the Department's adherence, and its recommendation or requirement within this chapter that members of the regulated community adhere, to these standards make the Department and members of the regulated community eligible to participate in Federal grant funding opportunities that support data modernization initiatives designed to encourage "minimum use" of electronic health recordkeeping technology. To the extent these standards could be considered Federal standards to which the rules at N.J.A.C. 8:57 are subject under the terms and conditions of Federal grant funding agreements, the proposed amendments, recodifications, repeals, and new rules at N.J.A.C. 8:57, would meet but not exceed these standards.

As the Summary, above, describes, the proposed amendments, recodifications, repeals, and new rules at N.J.A.C. 8:57 would be subject to the Federal standard articulated in the McKinney-Vento Homeless Assistance Act, 42 U.S.C. §§ 11431 through 11435. N.J.A.C. 8:57-4.2(d), as proposed for amendment, would require compliance with, but would not exceed, this applicable Federal standard, with respect to the period during which an administrator is to admit an unhoused person, to whom the Federal standard applies, to a school pending submission of evidence of immunization or immunity.

As the Summary, above, describes, pursuant to N.J.S.A 18A:75A-19, the Interstate Compact on Educational Opportunity for Military Children (Compact), and rules promulgated in accordance therewith, as amended and supplemented pursuant N.J.S.A. 18A-75A-13, the Military Interstate Children's Compact Commission (MIC3), would apply to the proposed amendments, recodifications, repeals, and new rules at N.J.A.C. 8:57. The MIC3 rules supersede and preempt any State requirement to demonstrate a minor's immunization or immunity in accordance with ACIP recommendations. Proposed new N.J.A.C. 8:57-4.9 at subsection (c) would require compliance with, but would not exceed, this standard with respect to the period during which an administrator is to permit a student or collegian, who is a military child to whom the Compact applies, to attend provisionally pending submission of evidence of immunization or immunity.

The Department promulgates the rules at Subchapter 5 to comply with State statutes requiring the identification, treatment, management, and confinement of persons with suspected or confirmed TB, which the rulemaking Authority, above, identifies. The Department receives funding from the Agency for Toxic Substances and Disease Registry of the CDC, pursuant to a Federal Award Project entitled Tuberculosis Elimination and Laboratory Cooperative Agreement (Award) that is intended to support prevention and control activities and laboratory services to reduce TB morbidity and mortality, prevent transmission of TB, and prevent progression from latent TB infection to active TB disease.

The rules at N.J.A.C. 8:57-5 facilitate the Department's compliance with the terms and conditions of the Award by enabling the Department to ensure the

compliance of, and collect Statewide data and information from, its local partners throughout the State relating to the State's efforts toward the advancement of the Award's goals. These partners include local health agencies, health care facilities, correctional facilities, clinical laboratories, institutions, and other entities with compliance and reporting obligations. The Department in turn can comply with required reporting to the CDC as to the State's use of the Award and its achievement of performance measures and other deliverables. These reports address the State's efforts to diagnose and treat persons with TB disease and persons with latent TB infection; examine immigrants and refugees who have an overseas B classification for TB; strategically direct testing for, and treatment of, latent TB infection; engage in program planning, evaluation, and improvement activities; perform epidemiologic surveillance and response; facilitate human resource development and partnership activities; and strengthen public health laboratory services. The existing rules at Subchapter 5, and the proposed amendments thereto, would meet but not exceed the terms and conditions of the Award.

Except as described above, the Department does not propose the amendments, repeals, recodifications, and new rules under the authority of, or 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.

Jobs Impact

The proposed repeals, new rules, recodifications, and amendments at N.J.A.C. 8:57 could maintain or increase demand for administrative, health information, data privacy, information technology, and healthcare professionals, at institutions upon which the rules would impose the same or additional data collection, recordkeeping, and reporting obligations using information technology and other recordkeeping systems. Required activities would continue to include collecting and maintaining records, making records available for public health official inspection, and ensuring that records are compliant with applicable content requirements.

The Department is unable to estimate the number of jobs that would be maintained or increased, as this would depend on the type and size of the institution, the nature of its operations, and the number of persons it serves, all of which would affect the amount of data the institution would generate that would be subject to the chapter's data collection, recordkeeping, and reporting requirements. To the extent the rules would require institutions to train personnel to use existing or new information technology systems, the proposed repeals, new rules, recodifications, and amendments at N.J.A.C. 8:57 could maintain or increase demand for instructors to provide this training.

Agriculture Industry Impact

N.J.A.C. 8:57-2.7, as proposed for recodification with amendment from -1.8, would require a veterinarian, a certified animal control officer, an animal facility manager, and an animal rescue organization to report suspected or confirmed rabies in livestock (or any other type of animal, including a domestic companion animal), to

facilitate proper case investigation and potential quarantine of other exposed animals. The rule would continue to require the Department to notify the Secretary of Agriculture upon receiving a report indicative of a suspected or confirmed reportable zoonotic disease or an outbreak of any disease that could affect animals, plants, or crops under the Secretary's jurisdiction. Except as described above, the proposed amendments, repeals, recodifications, and new rules at N.J.A.C. 8:57 would not have an impact on the agricultural industry of the State.

Regulatory Flexibility Analysis

The proposed amendments, repeals, recodifications, and new rules at N.J.A.C. 8:57 would establish standards applicable to healthcare professionals, clinical laboratory directors, health officers, veterinarians, certified animal control officers, animal facility managers, and employers, and other persons in charge, at food establishments, drug establishments, and cosmetic establishments. In addition, the proposed amendments, repeals, and new rules at N.J.A.C. 8:57 would establish standards applicable to administrators of the following: health care facilities, correctional facilities, other State operated or licensed facilities, schools, youth camps, child care centers, institutions, farm and migrant labor camps, and insurers.

The entities listed above, other than hospitals, certain large institutions, and government-operated facilities or agencies, could be small businesses within the meaning of the New Jersey Regulatory Flexibility Act, N.J.S.A. 52:14B-16 et seq. The Summary, above, describes the reporting, recordkeeping, and compliance requirements applicable to entities subject to the chapter. The Economic Impact and Jobs Impact

above, describe the costs of compliance and the need for retention of professionals to comply.

The Department has determined that the proposed amendments, repeals, recodifications, and new rules at N.J.A.C. 8:57 would establish the minimum standards necessary for the Department to fulfill its various statutory public health oversight mandates, protect the public from the spread of communicable and vaccine-preventable diseases, and maintain accurate public health data. Therefore, the Department proposes no lesser or differing standards for small businesses than those that would apply to all businesses. However, the proposed amendments, repeals, and new rules necessarily self-scale the compliance burden to business size. For example, the number of reports that the chapter would require entities to submit to the NJIIS or the CDRSS would depend on the number of persons the small business serves who generate reportable data.

Housing Affordability Impact

The Department anticipates that the proposed amendments, repeals, recodifications, and new rules at N.J.A.C. 8:57 would not have an impact on affordable housing in New Jersey and would not evoke a change in the average costs associated with housing because the proposed amendments, repeals, recodifications, and new rules would establish procedures for public health reporting and oversight and would not have any bearing on housing costs.

Smart Growth Development Impact

The proposed amendments, repeals, recodifications, and new rules at N.J.A.C. 8:57 would have no impact on smart growth and would not evoke a change in housing production in Planning Areas 1 or 2 or within designated centers under the State Development and Redevelopment Plan in New Jersey because the proposed amendments, repeals, recodifications, and new rules, would establish procedures for public health reporting and oversight and would not have any bearing on housing production.

Racial and Ethnic Community Criminal Justice and Public Safety Impact

The Department has evaluated this rulemaking and determined that it will not have an impact on pretrial detention, sentencing, probation, or parole policies concerning adults and juveniles in the State. Accordingly, no further analysis is required.

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 rules proposed for repeal may be found in the New Jersey Administrative Code at N.J.A.C. 8:57-1.1, 1.2, 1.12, 2.1, 3.2, 3.3, 3.17, 3.18, 3.21, 8:57-3 Appendix E and G, 4.7, 4.9 through 4.21, 4.23, 6.1 through 6.16, and 6.18 through 6.21.

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

CHAPTER 8

COLLECTION, PROCESSING, STORAGE AND DISTRIBUTION OF BLOOD

SUBCHAPTER 5. RECORDS AND REPORTING REQUIREMENTS

8:8-5.2 Reporting requirements

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

(c) Blood banks shall report prospective donors testing positive for hepatitis B, hepatitis C, syphilis and infectious diseases that are reportable pursuant to N.J.A.C. 8:57[-1] to the Communicable Disease Service of the Department or the local health agency in accordance with N.J.A.C. 8:57[-1].

(d)-(g) (No change.)

CHAPTER 25

NEW JERSEY YOUTH CAMP SAFETY STANDARDS

SUBCHAPTER 1. GENERAL PROVISIONS

8:25-1.4 Definitions

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

…

"Communicable disease" shall have the meaning established at N.J.A.C. 8:57[-1].

…

SUBCHAPTER 5. HEALTH

8:25-5.5 Health records

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

(d) All campers shall:

1. Be immunized, with the vaccinations required for child-care center, preschool**,** or school attendance, as appropriate for the camper's age, according to the immunization schedule set forth at [Immunization of Pupils in School,] N.J.A.C. 8:57[-4]; or

2. (No change.)

(e) The youth camp shall adhere to the requirements established at N.J.A.C. 8:57[-4.3(a) and (b)] regarding [medical] exemption[s for] **of a** camper[s] from immunization[, where the immunization is medically contraindicated] **based on medical contraindication**.

1. (No change.)

(f) The youth camp shall adhere to the requirements established at **N.J.S.A. 26:12-16 and** N.J.A.C. 8:57-4[.4(a)] regarding religious exemption[s for] **of a** camper[s] from immunization.

1. (No change.)

(g) (No change.)

CHAPTER 28

TANNING FACILITIES

SUBCHAPTER 1. GENERAL PROVISIONS

8:28-1.2 Definitions

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

…

"Communicable disease" means **communicable** disease[s or conditions as defined in] **pursuant to** N.J.A.C. 8:57[-1].

…

CHAPTER 36

STANDARDS FOR LICENSURE OF ASSISTED LIVING RESIDENCES, COMPREHENSIVE PERSONAL CARE HOMES, AND ASSISTED LIVING PROGRAMS

SUBCHAPTER 18. INFECTION PREVENTION AND CONTROL SERVICES

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] **communicable** diseases contracted by employees during employment, as specified at N.J.A.C. 8:57[-1.5].

CHAPTER 39

STANDARDS FOR LICENSURE OF LONG-TERM CARE FACILITIES

SUBCHAPTER 19. MANDATORY INFECTION CONTROL AND SANITATION

8:39-19.4 Mandatory general policies and procedures for infection control and sanitation

(a)-(e) (No change.)

(f) The facility shall have a system for investigating, evaluating, and reporting the occurrence of all reportable infections and diseases as specified in [Chapter II of the State Sanitary Code (]N.J.A.C. 8:57[-1)].

(g)-(n) (No change.)

SUBCHAPTER 27. MANDATORY QUALITY OF CARE

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] **pursuant to** N.J.A.C. **8:9 and** 8:57[-1.3] shall be tagged accordingly before being released from the facility.

(f) (No change.)

CHAPTER 43A

MANUAL OF STANDARDS FOR LICENSING OF AMBULATORY CARE FACILITIES

SUBCHAPTER 14. INFECTION PREVENTION AND CONTROL SERVICES

8:43A-14.2 Infection control policies and procedures

(a) (No change.)

(b) The infection control committee, with assistance from each service in the facility, shall develop, implement, and review, every three years or more frequently, as necessary, written policies and procedures regarding infection prevention and control, including, but not limited to, policies and procedures regarding the following:

1. In accordance with N.J.A.C. 8:57 [(Communicable Diseases)]**,** a system for investigating, reporting, and evaluating the occurrence of all infections or diseases which are reportable or conditions which may be related to activities and procedures of the facility;

2. Identifying and reporting [of] HIV[/AIDS] **infection** as specified in N.J.A.C. 8:[57-2]**65**, **HIV Infection** Reporting [of Acquired Immunodeficiency Syndrome and Infection with Human Immunodeficiency Virus];

3.-9. (No change.)

CHAPTER 43D

STANDARDS FOR LICENSURE OF PEDIATRIC COMMUNITY TRANSITIONAL HOMES

SUBCHAPTER 15. INFECTION PREVENTION AND CONTROL SERVICES

8:43D-15.4 Employee health and resident policies and procedures for infection prevention and control

(a)-(k) (No change.)

(*l*) The facility shall maintain records documenting communicable diseases contracted by employees during employment or residents during their stay in the facility and

complete required reporting, as specified at N.J.A.C. 8:57[-1.3(a) and (b), 2 or 5], as applicable.

(m) (No change.)

CHAPTER 43G

HOSPITAL LICENSING STANDARDS

SUBCHAPTER 14. INFECTION CONTROL

8:43G-14.1 Infection control program structural organization

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

(d) The infection control program shall oversee, but not be limited to, the following activities:

1.-4. (No change.)

5. Identifying and reporting communicable diseases throughout the hospital, with the cooperation of the clinical laboratory, medical records, and the medical staff, as specified in N.J.A.C. 8:57[-1, “Reportable Communicable Diseases”]; and

6. Identifying and reporting of HIV[/AIDS as specified] **infection** in **accordance with** N.J.A.C. 8:[57-2 “]**65, HIV Infection** Reporting [of Acquired Immunodeficiency Syndrome and Infection with Human Immunodeficiency Virus].[”]

(e)-(g) (No change.)

SUBCHAPTER 19. OBSTETRICS

8:43G-19.15 Newborn care policies and procedures

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

(d) The newborn nursery shall identify and report any outbreak of disease, or any single case of disease as specified in N.J.A.C. 8:57[-1.1 through 1.5].

(e)-(h) (No change.)

CHAPTER 52

PUBLIC HEALTH PRACTICE STANDARDS OF PERFORMANCE FOR LOCAL BOARDS OF HEALTH IN NEW JERSEY

SUBCHAPTER 3. PUBLIC HEALTH PRACTICE

8:52-3.3 Local health agency's minimum capacity

(a) Each local health agency shall, at a minimum, have the capacity to deliver:

1.-6. (No change.)

7. All other public health services required by **N.J.A.C. 3A:52, 5:17, and 7:9A,** the State Sanitary Code (N.J.A.C. 8:21, 8:22, 8:23, 8:23A, 8:24, 8:25, 8:26, 8:27, 8:51, and 8:57[-1 through 4, 10:122, 5:17 and 7:9A]**)**, and N.J.S.A. 24:14A-1 et seq., 26:3-69.1**,** and 58:11-23[);]**,** unless the population or entity requiring the services does not exist within the local health agency's jurisdiction or the services are otherwise assured through formal written linkages with another local health agency;

8.-10. (No change.)

SUBCHAPTER 12. DIAGNOSIS AND INVESTIGATION OF HEALTH PROBLEMS AND HAZARDS

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[-1.5]. This mechanism shall be capable of operating 24 hours per day, seven days per week, including weekends and holidays.

SUBCHAPTER 14. ENFORCEMENT OF PUBLIC HEALTH LAWS

8:52-14.1 Scope and purpose

This subchapter addresses the enforcement of **N.J.A.C. 3A:52, 5:17, and 7:9A,** the State Sanitary Code (N.J.A.C. 8:21, 8:22, 8:23, 8:23A, 8:24, 8:25, 8:26, 8:27, 8:51, **and** 8:57[-1 through 4, 10:122, 5:17**,** and 7:9A]**)**, and N.J.S.A. 24:14A-1 et seq., 26:3-69.1**,** and 58:11-23[)]; the protection of food and potable water supplies; **and** environmental health activities related to air, water, noise, and public health nuisances and health hazards, preventable injuries, and exposure-related diseases in both the workplace and community settings.

N.J.A.C. 8:52

APPENDIX

PROGRAMMATIC GUIDELINES FOR BEST PRACTICES

I. Environmental Health Activities

Recreational Bathing

(a) The local board of health shall:

1. (No change.)

2. Inspect, using an inspection form designed by the Department of Health [and Senior Services], each public bathing place at least twice during the operating season, make follow-up inspections when deficiencies are found, and take necessary enforcement actions;

3.-4. (No change.)

5. Conduct investigations within 24 hours of all deaths and serious injuries and report such occurrences [as outlined] in [the Recreational Bathing Regulations (] **accordance with** N.J.A.C. 8:26[)]**, Public Recreational Bathing,** on a form developed by the Department of Health [and Senior Services].

…

Youth camps

(a) The local board of health shall conduct a youth camp sanitation and safety program (N.J.A.C. 8:25) and shall:

1.-2. (No change.)

3. Submit copies of each inspection to Consumer and Environmental Health Services, Department of Health [and Senior Services].

Food surveillance

(a) The local board of health shall maintain surveillance of retail food establishments, food and beverage vending machines and shall:

1. (No change.)

2. Inspect retail food establishments using forms approved by the Department of Health [and Senior Services] at least once a year, inspect vending machines dispensing

potentially hazardous foods at least once a year and those dispensing non-potentially hazardous foods on a complaint basis or as required by local ordinance;

3.-7. (No change.)

8. Assist the Department of Health [and Senior Services] upon request in conducting recalls and recall effectiveness checks of foods found to be contaminated, adulterated**,** or misbranded; and

9. (No change.)

Occupational health (operative January 1, 1989)

(a) The local board of health shall conduct an occupational health program operative January 1, 1989; and shall:

1.-2. (No change.)

3. Train or obtain at least one staff person in Occupational Health and Industrial Hygiene through a continuing education program provided or made available by the Occupational Health Services of the Department of Health [and Senior Services];

4. Conduct initial and follow-up interviews, utilizing standardized procedures and forms developed by the Department of Health [and Senior Services], upon receipt of reports of occupational disease cases (N.J.A.C. 8:[57-1.13]**58**); and

5. Conduct preliminary surveys in response to reported occupational diseases or referrals from the Department of Health [and Senior Services], using standardized forms provided by the Department of Health [and Senior Services] to record observations and collect information. (These standardized forms shall be forwarded to the Department of Health [and Senior Services']**,** Occupational Health Services**,** for follow-up).

…

II. Communicable Disease Activities

Reportable diseases

(a) The local board of health shall conduct a program for the surveillance, investigation and control of reportable diseases and shall:

1. Document episodes of reportable diseases including occupational diseases and/or incidents and transmit the information to the State and other agencies as required by [chapter 2, Reportable Diseases (]N.J.A.C. 8:57[-1) of the State Sanitary Code] **and 8:58,** and N.J.S.A. 26:4;

2. Conduct prompt investigations of reportable illnesses as well as unusual manifestations of disease not listed as reportable in [chapter 2 of the State Sanitary Code (]N.J.A.C. 8:57[-1)] and **8:58,** institute appropriate control measures, and promptly report all findings to the Department of Health [and Senior Services];

3.-4. (No change.)

Immunization

(a) The local board of health shall promote and provide immunizations for protection against childhood vaccine-preventable diseases and shall:

1. Promote and provide primary and booster immunizations to preschool and school age children for protection against diseases in accordance with current recommendations of the Department of Health [and Senior Services];

2. Assist all schools, with an emphasis on preschool facilities, in implementing and enforcing the immunization requirements contained in [Chapter 14, of the State

Sanitary Code (]N.J.A.C. 8:57[-4)] by providing immunization services and conducting periodic surveys and representative record audits every year;

3. Secure prompt reporting of vaccine-preventable disease as required by [chapter 2 of the State Sanitary Code (]N.J.A.C. 8:57[-1.2)]; and

4. (No change.)

Rabies and zoonosis control

(a) The local board of health shall conduct a program for the control of rabies and other zoonoses and shall:

1.-2. (No change.)

3. Inspect kennels, pet shops, shelters**,** and pounds, to ensure compliance with the State laws and regulations prescribed by the Department of Health [and Senior Services], and ensure that licenses issued to these facilities are in compliance with existing laws;

4. Report and investigate animal bites, ensure that persons bitten are advised to see a physician, quarantine biting animals as indicated and report immediately to the Department of Health [and Senior Services] clinically suspicious cases of rabies in animals as determined by a veterinarian, ensure availability of impounding facility where biting animals may be appropriately quarantined and observed for rabies;

5. Ensure that heads of animals that have died within 10 days after biting a person are delivered immediately to the Department of Health [and Senior Services']**,** Public Health and Environmental Laboratories for examination (Unwanted dogs or cats or any another animal which has bitten a human may be sacrificed immediately and the

head promptly delivered to the Public Health and Environmental Laboratories for examination);

6. (No change.)

7. Inspect annually, or more often**,** if necessary, records of dealers in [psittacine] **pet** birds as required by [chapter] **Chapter** 3 of the State Sanitary Code (N.J.A.C. 8:23); and

8. (No change.)

Tuberculosis control

(a) The local board of health shall control the spread of tuberculosis and shall:

1. Ensure that all of the tuberculosis control services or services elements listed in the “Guidelines for Ambulatory or Outpatient Tuberculosis Control” (available at the New Jersey Department of Health [and Senior Services]) are available and accessible to all persons living within the jurisdiction of the local agency;

2. Secure prompt reporting of tuberculosis and transmit reports as required by the State Sanitary Code (N.J.A.C. 8:57[-1.2]) and encourage the reporting of suspects;

3. (No change.)

4. Ensure that [contracts] **contacts** are identified and brought to examination, diagnostic conclusion, and treatment in accordance with the policy of the Department of Health [and Senior Services];

5. Ensure the provision of preventive therapy in accordance with current recommendations of the Department of Health [and Senior Services];

6. Ensure reporting of the current status of diagnosed cases of tuberculosis in accordance with the policy of the Department of Health [and Senior Services] using forms provided by the State;

7. Provide for the discharge from tuberculosis supervision of patients whose treatment has been completed in accordance with current recommendations by the Department of Health [and Senior Services];

8. Provide for testing using currently approved intradermal tuberculin tests, of pupils, teachers, employees, and volunteers in the non-public schools, and for follow-up of those in both the public and non-public schools as recommended in the current edition of “School Tuberculin Testing in New Jersey,” published by the Department of Health [and Senior Services]; and

9. (No change.)

Sexually transmitted diseases

(a) The local board of health shall control sexually transmitted diseases and shall:

1. (No change.)

2. Secure prompt reporting of any case of STD and forward reports immediately to the Department of Health [and Senior Services], [Communicable Disease Field Program] **Division of HIV, STD, and TB Services**, [as required by chapter 2 of the State Sanitary Code (] **in accordance with** N.J.A.C. 8:57[-1.2)];

3. Provide interview and investigation services to priority STD cases in accordance with the policy established by the Department of Health [and Senior

Services] and report results of these services on appropriate forms provided by the Department;

4.-6. (No change.)

Human Immunodeficiency Virus (HIV) infection

(a) The local board of health shall administer a planned program to prevent and control HIV infection and shall:

1. Utilizing seroprevalence and case reporting data provided by the Department of Health [and Senior Services], identify ways to reach persons at high risk within the community and develop and implement a strategy to disseminate HIV prevention and control information to these groups;

2.-7. (No change.)

III. Maternal and Child Health Activities

Infants and preschool children

(a) The local board of health shall provide health supervision for infants and preschool children and shall:

1. Provide child health conferences for comprehensive preventive health care of infants and preschool children, with particular emphasis on the medically indigent, based upon the current Department of Health [and Senior Services] publication, “Guidelines For the Child Health Conference”;

2. Prepare a Child Health Service Report CH-7 or subsequent form number for each session, and submit promptly on at least a quarterly basis to the Maternal and Child Health Program in the [New Jersey] Department of Health [and Senior Services];

3.-4. (No change.)

Childhood lead poisoning

(a) The local board of health shall provide for the prevention and control of lead poisoning in young children and shall:

1. (No change.)

2. Develop a program plan based on elements in (a)1 above and on the degree of risk in the community as identified through the “Community Health Profile” and “Community Hazard Score for Lead Poisoning in Children” issued by the Department of Health [and Senior Services];

3.-6. (No change.)

Improved pregnancy outcome

(a) The local board of health shall reduce infant mortality by improving access to prenatal care and related services in accordance with guidelines established by the Department of Health [and Senior Services] and shall:

1.-4. (No change.)

5. Cooperate with the Department of Health [and Senior Services], Newborn Biochemical Screening Program to locate and secure repeat specimens from infants

when the sample cannot be obtained through the normal channels of a hospital and/or physician.

IV. Adult Health Services Activities

Cancer services

(a) The local board of health shall provide cancer prevention for populations at high risk according to criteria outlined in the Department of Health [and Senior Services'] publication**,** "Adult Health Services Guidelines**,**" and as identified through the Community Health Profile and shall:

1.-4. (No change.)

5. Provide yearly instruction to three percent of individuals over age 40 in these particular areas:

i. (No change.)

ii. The importance of compliance with the guidelines on colon/rectal cancer prescribed in Department of Health [and Senior Services'] Adult Health Services Guidelines; and

iii. (No change.)

6.-9. (No change.)

Diabetes services

(a) The local board of health shall provide for diabetes education services per the Department of Health [and Senior Services'] "Adult Health Services Guidelines" and shall:

1.-4. (No change.)

Cardiovascular disease services

(a) The local board of health shall provide cardiovascular disease control services according to the Department of Health [and Senior Services] “Adult Health Services Guidelines” and shall:

1.-5. (No change.)

Health services for older adults

(a) The local board of health shall provide for a health program at locations selected by the health department which identifies the health needs of adults age 65 and older, and shall:

1. Provide a health needs assessment yearly on one percent of the non-institutionalized elderly in accordance with “Guidelines for Health Services for Older Adults” contained in the Adult Health Services Guidelines (available at the [New Jersey] Department of Health [and Senior Services]);

2.-6. (No change.)

V. Health Education/Health Promotion

(a) A structured program shall be provided by the Health Educator or Field Representative, Health Education, in accordance with community health education needs, which shall include health components for Alcohol Abuse Control, Drug Abuse

Control, Smoking Prevention and Cessation, Nutrition, Injury Control, and Physical Fitness and Exercise and shall include the following:

1. An assessment of health education needs and identification of target population based on information from the New Jersey Department of Health [and Senior Services] Community Health Profile and other relevant health related data;

2.-8. (No change.)

…

CHAPTER 57

REPORTABLE COMMUNICABLE DISEASES**, INFECTIONS, AND CONDITIONS; REPORTABLE ZOONOTIC DISEASES OCCURRING IN ANIMALS; COMMUNICABLE DISEASE REPORTING AND SURVEILLANCE SYSTEM; NEW JERSEY IMMUNIZATION INFORMATION SYSTEM; CHILDHOOD IMMUNIZATION; AND IMMUNIZATION OF COLLEGIANS**

SUBCHAPTER 1. [REPORTABLE COMMUNICABLE DISEASES] **GENERAL PROVISIONS**

REPEAL AND NEW RULE: 8:57-1.1 Purpose and scope

8:57-1.1 Purpose

(a) The purpose of this chapter is to establish standards:

1. For detection, reporting, investigation, and control of communicable diseases, infections, and conditions pursuant to N.J.S.A. 26:4-1 et seq., and reportable zoonotic diseases occurring in animals pursuant to N.J.S.A. 4:19-15.14 et seq., and 26:4-78 et seq.;

2. For the Communicable Disease Reporting and Surveillance System;

3. For an automated and electronic immunization registry, known as the "New Jersey Immunization Information System," pursuant to the Statewide Immunization Registry Act, N.J.S.A. 26: 4-131 et seq.;

4. For childhood immunization pursuant to N.J.S.A. 26:1A-7 and 26:2-137.1; and

5. For immunization of collegians entering and attending institutions of higher education pursuant to N.J.S.A. 18A:61D-1 et seq., and 18A:62-15.1 and 15.2.

REPEAL: 8:57-1.2 Incorporated documents

8:57-[1.3]**1.2** Definitions

The following words and terms, as used in this 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.]**:**

"AAP Red Book" means Kimberlin DW, Banerjee R, Barnett ED, Sawyer MH, eds., *Red Book: 2024 Report of the Committee on Infectious Diseases*, 33rd edition, American Academy of Pediatrics (2024), incorporated herein by reference, as amended and supplemented, available at https://www.aap.org/en/shopaap.

"Academic degree" means academic degree as N.J.A.C. 9A:1-1.2 defines that term.

“Academic term” means a semester or quarter within an academic year, as determined by an institute of higher education’s structure.

“ACIP recommendations” means the Child and Adolescent Immunization Recommendations, and the Adult Immunization Recommendations.

“Administrator” [shall] mean**s** the person [having control or supervision over a] **who controls or supervises the following types of facility, collectively, unless the context indicates a specific type of facility, in which case the term applies only to that type of facility:**

1. A health care facility[,]**;**

2. A correctional facility[,]**;**

3. A State psychiatric hospital as N.J.S.A. 30:1-7 and 4-3.23;

4. A facility under the jurisdiction of the New Jersey Department of Children and Families;

5. A facility under the jurisdiction of the New Jersey Department of Human Services;

6. A facility under the jurisdiction of the Youth Justice Commission of the New Jersey Department of Law and Public Safety;

7. A school[,]**;**

8. A youth camp[,]**;**

9. A child care center[, preschool, or]**;**

10. An institution [of higher education]**;**

11. A farm or migrant labor camp as N.J.S.A. 34:9A-2 defines those terms under the jurisdiction of the Department of Labor and Workforce Development pursuant to N.J.S.A. 34:9A-12;

12. An insurer as N.J.S.A. 17:23A-1 et seq., specifically 17:23A-13.1, and/or 17B:17-1 et seq., specifically 17B:12-2, use that term; and/or12. A residential health care facility that is:

i. Not located within, and operated by, a licensed health care facility; and

ii. Operating pursuant to N.J.S.A. 30:11A-3 and N.J.A.C. 5:27A under the jurisdiction of the Department of Community Affairs.

"Adult Immunization Recommendations" means:

1. CDC and ACIP, *Recommended Adult Immunization Schedule for ages 19 years or older, United States 2025* (August 7, 2025), including the Tables, Notes, Appendices, and Addendum thereto, incorporated herein by reference, as amended and supplemented, available at https://www.cdc.gov/vaccines/hcp/imz-schedules; and

2. CDC and National Center for Immunization and Respiratory Diseases, *General Best Practices for Immunization* (General Best Practices) (July 24, 2024), incorporated herein by reference, as amended and supplemented, available at https://www.cdc.gov/vaccines/hcp/imz-best-practices/index.html.

"Advisory Committee on Immunization Practices" or "ACIP" means the Advisory Committee on Immunization Practices, National Center for Immunization

and Respiratory Diseases, Centers for Disease Control and Prevention, 1600 Clifton Road NE, Mailstop H24-8, Atlanta, Georgia 30329-4027, Telephone: (404) 639-8836, electronic mail address acip@cdc.gov, and website https://www.cdc.gov/acip/index.html.

"Animal facility" [shall have the meaning established for] **means** "facility" [at] **as** N.J.A.C. 8:23A-1.1 **defines that term**.

"Animal rescue organization" means "animal rescue organization" as N.J.S.A. 4:19-15.1 defines that term.

"Billing vendor" means an entity that a healthcare professional retains to prepare invoices, claims, and/or statements of services performed by the professional and submit them to a third party for payment or reimbursement.

"Biologic" means a medicinal compound prepared from living organisms and their products.

"Bioterrorism" means "bioterrorism" as N.J.S.A. 26:13-1 et seq., specifically 26:13-2, defines that term.

"Birthing facility" means a health care facility that provides birthing and newborn care services and includes a "birth center" as N.J.A.C. 8:43G-19.1 defines that term.

"Carbapenemase gene" means DNA that encodes to produce enzymes that break down carbapenem drugs, such as blaKPC, blaNDM, blaVIM, blaIMP, blaOXA-48, blaOXA-23, blaOXA-24/40, blaOXA-58, blaDIM, blaSIM, blaGIM, and blaSPM.

"Carbapenemase-producing organism" or "CPO" means an organism that produces carbapenemase as evidenced by any of the following laboratory results:

1. Positive phenotypic test detecting or indicating carbapenemase production;

2. Positive genotypic test detecting one or more carbapenemase genes using a validated laboratory-developed platform; or

3. Positive culture-independent diagnostic test detecting one or more carbapenemase genes.

"Case" means a person who:

i. Has, or is suspected of having, a disease, infection, or condition that is reportable pursuant to N.J.A.C. 8:57-2; and/or

ii. Is, or is suspected of being, infected with an organism that is reportable pursuant to N.J.A.C. 8:57-2.

"Catch-up Schedule" means *Table 2, Recommended Catch-up Immunization Schedule for Children and Adolescents Who Start Late or Who Are More than 1 Month Behind, United States, 2025*, within the Child and Adolescent Vaccine Recommendations.

"CDC Laboratory Recommendations for Syphilis Testing" means Papp JR, Park IU, Fakile Y, Pereira L, Pillay A, Bolan GA, *CDC Laboratory Recommendations for Syphilis Testing, United States, 2024*, MMWR Recomm Rep 2024;73 (No. RR-1):1–32 (February 8, 2024), incorporated herein by reference, as amended and supplemented, available at

http://dx.doi.org/10.15585/mmwr.rr7301a1 and https://www.cdc.gov/mmwr/volumes/73/rr/pdfs/rr7301a1-H.pdf.

"Centers for Disease Control and Prevention" or "CDC" means the Centers for Disease Control and Prevention of the Public Health Service of the United States Department of Health and Human Services.

"Certified animal control officer" [shall have the meaning established at] **means "certified animal control officer" as N.J.S.A. 4:19-15.1 and** N.J.A.C. 8:23A-2.1 **define that term**.

"Child and Adolescent Immunization Recommendations" means:

1. CDC and ACIP, *Recommended Child and Adolescent Immunization Schedule for ages 18 years or younger, United States 2025* (August 7, 2025), including the Tables, Notes, Appendices, and Addenda thereto, incorporated herein by reference, as amended and supplemented, available at https://www.cdc.gov/vaccines/hcp/imz-schedules; and

2. CDC and National Center for Immunization and Respiratory Diseases, *General Best Practices for Immunization* (General Best Practices) (July 25, 2024), incorporated herein by reference, as amended and supplemented, available at https://www.cdc.gov/vaccines/hcp/imz-best-practices/index.html.

"Child care center" [shall have the meaning established at N.J.A.C. 10:122-1.2] **means:**

1. A "child care center," as the "Child Care Center Licensing Act," N.J.S.A. 30:5B-1 et seq., specifically at 30:5B-3, defines that term; and

2. An "early childhood program" as N.J.A.C. 3A:52-1.1 et seq., specifically 1.2 and 1.4, and 6A:14-1.3, define that term.

"Class B1 or B2 referral" means a referral from the Division of Global Migration Health, CDC, to the Department of a person who is a refugee, parolee, asylee, or recent legal immigrant to the USA, and whom an overseas medical provider screened and classified as either Class B1, meaning the individual has signs or symptoms, physical exam findings, or chest x-ray findings suggestive of tuberculosis, but has negative sputum smears and cultures, or Class B2, meaning the individual has a positive test for tuberculosis, but other evaluation for active tuberculosis is negative.

"Clinical laboratory" [shall have the meaning established at] **or "laboratory" means "clinical laboratory" as** N.J.S.A. 45:9-42.27 **defines that term**.

"Clinical laboratory director" [shall have the meaning established at] **means "clinical laboratory director" as** N.J.S.A. 45:9-42.27 **defines that term**.

"Collegian" means an undergraduate or a graduate student of an institution of higher education.

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

"Communicable disease" means [an illness due to a specific infectious agent or its toxic products which arises through transmission of that agent or its products from an infected person, animal, or inanimate reservoir to a susceptible host, either directly or indirectly through an intermediate plant or animal host, vector, or the inanimate environment] **"communicable disease" as N.J.S.A. 26:4-1 defines that term**.

“Communicable Disease Reporting and Surveillance System” or “CDRSS” means a secure electronic system that the Department uses and maintains, and through which entities with reporting obligations pursuant to this chapter engage in disease surveillance and case management, accessible at https://cdrss.nj.gov.

“Communicable Disease Service” or “CDS” means the Communicable Disease Service of the Division of Epidemiology, Environmental and Occupational Health of the Public Health Services Branch of the Department, for which the mailing address is PO Box 369, Trenton, NJ 08625-0369, the telephone number during business hours is (609) 826-5964, the telephone number after business hours is (609) 392-2020, the telefacsimile number is (609) 826-4874, and the webpage is https://www.nj.gov/health/cd.

“Condition” means a diagnosable health issue or illness identified through clinical evaluation, including the presence of characteristic signs and symptoms, diagnostic testing, or other medically accepted criteria.

"Contact" means a person whom a health official identifies as having had exposure:

1. To a case of suspected or confirmed infectious or potentially infectious tuberculosis; and

2. That is sufficient in both duration and proximity to make the person at increased risk for recent transmission of latent tuberculosis infection.

"Contraindication" means a condition in a person that increases the risk for a serious adverse reaction to a vaccine, under which a vaccine should not be administered to the person, as specified in the General Guidelines.

1. As used in this chapter, the term, "contraindication," may include a precaution, provided the statement that is required pursuant to N.J.A.C. 8:57-4.7 or 6.7:

i. Identifies the basis of the precaution, as specified in the General Guidelines and the period of deferral; and

ii. Contains a patient-specific analysis that explains how the risk of an adverse reaction to a vaccine would outweigh the benefit of protection from the vaccine.

"Cosmetic establishment" means "cosmetic establishment" as N.J.S.A. 24:15-1 defines that term.

"Council of State and Territorial Epidemiologists" or "CSTE" means the entity by that name for which the mailing address is CSTE, 2635 Century Parkway NE, Suite 700, Atlanta, GA 30345, the telephone number is (770) 458-3811, and the website is www.cste.org.

"Department" means the New Jersey Department of Health [and Senior Services] **for which the mailing or other transmittal information is as follows, unless otherwise specified:**

1. To the Division of HIV, STD, and TB Services as specified in N.J.A.C. 8:65, with respect to HIV-related submittals;

2. To the Division of HIV, STD, and TB Services with respect to submittals related to sexually transmitted diseases as specified in Subchapter 2 and/or tuberculosis as specified in Subchapter 5;

3. To the CDS with respect to submittals related to Subchapter 2, other than sexually transmitted diseases;

4. To the VPDP with respect to submittals related to Subchapters 4 or 6; and

5. To the NJIIS with respect to submittals related to Subchapter 3.

"Designated agent" means a person to whom a site administrator delegates responsibility pursuant to N.J.A.C. 8:57-3.8(b) to:

1. Submit information to the NJIIS;

2. Obtain access to information in the NJIIS;

3. Receive information from the NJIIS; and/or

4. Review information contained in the NJIIS.

"Directory of Local Health Departments in New Jersey" means Division of Local Public Health, Department, *Directory of Local Health Departments in New Jersey* (2025), which is an online resource available at http://www.nj.gov/health/lh/community.

"Division of HIV, STD, and TB Services" means the Division of HIV, STD, and TB Services of the Public Health Services Branch of the Department, for which the mailing address is Division of HIV, STD, and TB Services, NJ Department of Health, PO Box 363, Trenton, NJ 08625-0363, website https://www.nj.gov/health/hivstdtb, telephone:

1. HIV program (609) 984-5940

2. Tuberculosis program (609) 826-4878; and

3. STD program (609) 826-4869.

"Division of Local Public Health" means the Division of Local Public Health of the Public Health Services Branch of the Department, for which the mailing address is Division of Local Public Health, NJ Department of Health, PO Box 360, Trenton, NJ 08625-0360, the website is https://www.nj.gov/health/lh, and the telephone number is (609) 292-4993.

"DNA" means deoxyribonucleic acid.

"Domestic companion animal" [shall] mean**s** [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] **"domestic** companion animal**" as N.J.S.A. 4:19A-16 and 45:16-8.3 define that term and** 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.

"Drug establishment" means "drug establishment" as N.J.S.A. 24:15-1 defines that term.

“EBC” means the electronic birth certificate generated through the Vital Events Registration and Information platform.

“Electronic case reporting” means the automated, real-time exchange of case report information between an electronic recordkeeping system for health records and a public health agency.

“Electronic health record” or “EHR” means an individual patient’s comprehensive digital medical record., or a portion thereof.

“Electronic health record vendor” or “EHR vendor” means an entity that provides software and/or ancillary maintenance and administrative services to maintain an electronic system of recordkeeping for health records.

“Electronic laboratory reporting [(]**” or “**ELR[)]” means submission of laboratory test results [through] **in** an electronic file to [the Department’s Office of Information Technology Services’] **a** dedicated secure server [via Secure File Transfer protocol (] **of the Department using a secure file transfer protocol (**SFTP**)**, [Virtual Private Network] **virtual private network** (VPN), or any other secure transmission acceptable to the Department.

1. The **reporting entity shall submit the electronic file in the** format [of the electronic file must be one that is] specified in **either:**

i. The [Electronic Laboratory Reporting Technical Manual, available at subchapter Appendix A] **HL7 Implementation Guide; or**

ii. The NJ ELR Implementation Guide.

[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 subchapter Appendix A.]

"Electronic reporting" means submission of data [via] **by means of direct** 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.]

"Endemic level" means the usual prevalence of a given disease within a geographic area.

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

"Farm or migrant labor camp" means a "farm labor camp" or a "migrant labor camp" as N.J.S.A. 34:9A-2 defines those terms.

"FDA Food Code" means United States Food and Drug Administration, *Food Code, 2022 Recommendations of the United States Public Health Service, Food and Drug Administration* (January 18, 2023), incorporated herein by reference, as amended and supplemented, available at https://www.fda.gov/food/fda-food-code/food-code-2022

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“Food employee” means “food employee” as the FDA Food Code defines that term.

“Food establishment” means “food establishment” as N.J.S.A. 24:15-1 defines that term.

“Full-time collegian” means a collegian whom an institution of higher education enrolls for the number of credit hours or courses that the institution of higher education categorizes as full-time matriculation.

“Health benefits plan” means policy, contract, certificate, or agreement offered or issued by a health carrier to provide, deliver, arrange for, pay for, or reimburse any costs of healthcare services.

“Healthcare Effectiveness Data and Information Set®” or “HEDIS®” means the HEDIS® measurement tool created by the National Committee for Quality Assurance to collect data about the quality of care and services that health plans provide, and which is available from the National Committee for Quality Assurance, for which the mailing address is 1100 13th St NW, Third Floor, Washington, DC 20005, the telephone number is (202) 955-3500, and the website is www.ncqa.org.

“Health care facility” [shall have the meaning established at] **means “health care facility” as** N.J.S.A. 26:2H-2 **defines that term**.

“Healthcare personnel” means:

1. Paid and unpaid persons serving in healthcare settings who have potential direct or indirect exposure to patients or infectious materials, including:

i. Bodily substances (such as blood, tissue, and certain body fluids);

ii. Contaminated medical supplies, devices, and equipment; and

iii. Contaminated environmental surfaces or contaminated air;

2. Depending on a person's assigned job functions, emergency medical services personnel, advanced practice nurses, nurses, nursing assistants, physicians, physician assistants, technicians, therapists, phlebotomists, pharmacists, students and trainees, and contractual staff who work in, but are not employees of, a health care facility; and

3. Persons who work in a health care facility but do not engage in direct patient care and who have potential exposure to infectious agents that can be transmitted among direct care workers and patients, such as the following types of workers: clerical, dietary, environmental services, laundry, security, maintenance, engineering and facilities management, administrative, billing, and volunteer.

"Healthcare professional" means a person who holds a credential to provide health services pursuant to Title 45 of the New Jersey Revised Statutes and its implementing rules, and whose authorized scope of practice includes the diagnosis of illness or disease, including a communicable disease, infection, or condition in humans.

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"Health History and Appraisal form" means New Jersey Department of Education, *State of New Jersey Health History and Appraisal* (Form A-45), incorporated herein by reference, as amended and supplemented, available at https://www.nj.gov/education/safety/health/records.

"Health information exchange" or "health information network" means "health information network or health information exchange" as 45 CFR § 171.102 defines that term (hereinafter referred to respectively as an HIE or an HIN).

"Health information organization" or "HIO" means a legal entity comprising at least two, distinct, corporate entities that share and/or exchange health information and other patient care data.

"Health officer" means [a person who is licensed as a health officer pursuant to N.J.S.A. 26:1A-38, et seq. and N.J.A.C. 8:7-1 and is employed full-time, as the chief executive] **"health** 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] **as N.J.S.A. 26:3A2-3 defines that term**.

1. The Directory of Local Health Departments in New Jersey contains the mailing address, telephone number, and, if available, the website and other transmittal information for each local health agency and health officer in the State.

"HL7 Implementation Guide" means Health Level Seven International, *HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health, Release 1 (US Realm)*, (2021), incorporated herein by reference, as amended and supplemented, available at https://www.hl7.org/implement/standards/product_brief.cfm?product_id=98, or from Health Level Seven International, 3300 Washtenaw Avenue, Suite 227, Ann Arbor, MI 48104, telephone (734) 677-7777, website https://www.hl7.org.

"Hospital" means a hospital as N.J.A.C. 8:43G-1.3 defines that term.

"Hospital-onset [methicillin-resistant *Staphylococcus aureus* (]MRSA[)] invasive infection[s]" means an [isolation] **identification** of **the presence of** MRSA **in a specimen** from a normally sterile site, such as blood, [cerebro-spinal fluid] , or **cerebrospinal,** joint, pleural, or pericardial fluid, greater than 48 hours after admission to [the] **a** hospital.

"Immunization" means:

1. An immunizing agent, typically referred to as a vaccine; or

2. The process and procedures associated with introducing an immunizing agent into a person to prevent disease, also referred to as a vaccination.

"Infection" means the invasion and multiplication of a pathogenic microorganism in the body, which may include a bacterium, virus, fungus, parasite, or other agent capable of causing disease.

"Influenza **A** virus, novel [strain]" [shall mean a virus subtype that is different from the human influenza A viruses that have been circulating that influenza season] **means**

"novel influenza A virus infection" as the Surveillance Case Definition defines that term.

"Institution" means a health care facility, a youth camp, a child care center, a school, and an institution of higher education.

"Institution of higher education" or "IHE" means a public or independent institution of higher education in New Jersey and includes on-campus and off-campus facilities, premises, and events that the IHE authorizes or sponsors, or at which collegians might congregate.

1. An IHE does not include an institution that:

i. Exclusively provides instruction by means of independent home study and/or electronic media; and

ii. Does not sponsor or authorize, or require collegians to congregate at, on-campus or off-campus facilities or events for instructional, educational, or extracurricular activity purposes.

"Insurer" means "insurer" as N.J.S.A. 17:23A-13.1 or 17B:17-2 use that term.

"Invalid dose" means a dose of a vaccination that, in accordance with N.J.A.C. 8:57-4 and/or applicable ACIP recommendations:

1. Is age-inappropriate for a recipient when the recipient receives the dose; and/or

2. Is spaced inappropriately following a prior dose that the recipient received.

"Invasive disease" means an infection that [has invaded] **invades** body tissues and **an identification of** the **disease's** causative bacterium [has been isolated] **in a specimen** from **a normally sterile site, such as** blood, **or** cerebrospinal [fluid], **joint,** pleural**, or pericardial** fluid [or other normally sterile site].

"Isolation" [shall have the meaning established at] **means "isolation" as** N.J.S.A. 26:13-2 **defines that term**.

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

["Local health department" means the board of health of a region or municipality or the boards, bodies, or officers in such region or municipality lawfully exercising any of the powers of a local board of health under the laws governing such region or municipality.]

"Line list" means a table summarizing information about cases associated with an outbreak, the required content of which the Department identifies upon notification of the outbreak, depending on the disease and the manner of disease transmission, in which each row represents a specific case (containing identifying information), and each column represents a specific demographic (such as age or race), clinical data (such as dates of onset of symptoms, symptomology, and outcome), or epidemiologic characteristic about each case (such as location at which exposure occurred and occupational information).

"Local health agency" means "local health agency" as N.J.S.A. 26:2F-3 defines that term.

1. The Directory of Local Health Departments in New Jersey contains the mailing address, telephone number, and, if available, the website and

other transmittal information for each local health agency and health officer in the State.

"Local Information Network and Communications System" or "LINCS" means "Local Information Network and Communications System" or "LINCS" as N.J.A.C. 8:52 defines that term.

"Logical Observation Identifiers Names and Codes®," or "LOINC" means Regenstrief Center for Biomedical Informatics, *Logical Observation Identifiers Names and Codes*®, version 2.80 (February 2025), incorporated herein by reference, as amended and supplemented, available at http://www.loinc.org.

"Manager" means the person who has control or supervision of an animal facility or animal rescue organization.

"Maternal and Child Health Consortia" or "MCHC" means "Maternal and Child Health Consortia" or "MCHC" as N.J.A.C. 8:33C-1.2 defines that term.

"Methicillin-resistant *Staphylococcus aureus* [(]**" or "**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) available as set forth at N.J.A.C. 8:57-1.2(b)] **PSAST**.

["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).]

"Minor" means a person who has not attained majority status pursuant to N.J.S.A. 9:17B-1 et seq., that is, a person who is under the age of 18 years.

"Morbidity and Mortality Weekly Report" or "MMWR" means the serial publication by that name published by the Office of Science, CDC, United States Department of Health and Human Services, Atlanta, GA 30329-4027, available at http://www.cdc.gov/mmwr/index.html"MRSA laboratory identification event" or "MRSA LabID event" means a laboratory's identification of MRSA in a blood sample.

"Neonatal" [shall mean] **means occurring in** a [child less than 90 days of age] **newborn**.

["Nosocomial infection" means an infection occurring in a patient in a 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 health care facility but appearing after discharge, and also such infections among the staff of the facility.]

"Newborn" means a minor who is 28 or fewer days old.

"New Jersey Immunization Information System" or "NJIIS" means the registry established pursuant to N.J.S.A. 26:4-131 et seq.

"NJ ELR Implementation Guide" means Department, *Electronic Laboratory Reporting Inbound HL7 Implementation Guide*, Version 2.40 (June 26, 2014)

(hereinafter referred to as the NJ ELR Implementation Guide), as amended and supplemented, at https://cdrss.nj.gov/cdrss/common/cdrssELREnrollment.

"NJIIS access level" means the information in, and functions of, the NJIIS that an NJIIS user is authorized to view, enter, change, and/or administer, from among the following levels:

1. "General reader access" means access to view registrant records and generate standard reports;

2. "General user access" means general reader access and access to modify or add information to existing registrant records, add new registrants, maintain vaccine inventory, and perform outreach functions to registrants for whom the NJIIS site has primary responsibility;

3. "NJIIS site administrator access" means general user access, plus access to modify critical fields and maintain vaccine inventory control records;

4. "Educational facility user access" means general reader access, plus access to modify or add information to existing registrant records, add new registrants, and perform outreach functions to registrants who are then-enrolled, and/or have a pending application to enroll, in the educational facility, which is an institution, school, or child care center; or

5. "Health benefits plan access" means access for health benefits plan users to run HEDIS® and other data quality assurance reports, and for the purposes established at N.J.S.A. 26:4-134*i(7)*.

“NJIIS Personal Immunization Record” means a paper or electronic version of a registrant's immunization and preventive health screening information that is a true and accurate representation of the information contained in the NJIIS and that is not a part of a minor's educational record.

“NJIIS site” coordinates the administrative functions and activities for its NJIIS users and means one of the following entities:

1. A healthcare professional;

2. An early childhood program;

3. A school;

4. An institution;

5. A hospital or health care facility;

6. A health benefits plan;

7. A billing and practice management vendor;

8. A private health or social services program;

9. A local health agency of:

i. A municipal subdivision of New Jersey; or

ii. An entity within the meaning of the term, “USA”;

10. A State agency;

11. An EHR vendor authorized pursuant to N.J.S.A. 26:4-134(c) and (g) and N.J.A.C. 8:57-3.9; and

11. An HIE, HIN, or HIO.

“NJIIS site administrator” means a person who enrolls an eligible entity in the NJIIS as an NJIIS site and who serves as liaison to the Department with

respect to enrollment of NJIIS users at the NJIIS site and resolution of NJIIS administrative and information technology matters.

"NJIIS user" means a person who, acting on behalf and under the authority of an NJIIS site, obtains access or submits information to, and/or receives or reviews information contained in, the NJIIS.

"NJIIS webpage" means the webpage of the NJIIS at https://www.njiis.nj.gov/core/web/index.html#/home.

"NJ Medicaid Program" means the health insurance program administered by the Division of Medical Assistance and Health Services in the Department of Human Services pursuant to the New Jersey Medical Assistance and Health Services Act, N.J.S.A. 30:4D-1 et seq., also known as NJ FamilyCare.

"Notifiable Condition List" means CDC, *National Notifiable Infectious Diseases of the National Notifiable Diseases Surveillance System*, available at https://ndc.services.cdc.gov.

"Nucleic acid amplification test" means a laboratory test that detects and amplifies specific DNA or RNA sequences for the organism being tested.

"Nursing home" or "nursing facility" means "nursing home" or "nursing facility" as N.J.A.C. 8:33H-1.2 defines that term.

"Official State of New Jersey School Immunization Record" means:

1. Standard School/Child Care Center Immunization Record, provided at Appendix K;

2. Health History and Appraisal form or any equivalent electronic record maintained by a school district pursuant to N.J.A.C. 6A:16-2 or 6A:32-7; or

3. A paper or electronic version of an NJIIS Personal Immunization Record, including a record the Docket® mobile phone application or Docket® website application at https://myhealthnj.com, or a successor application administered by an entity with which the Department may elect to enter into a cooperative data sharing agreement.

"Outbreak" means [any]**:**

1. An unusual occurrence of **a** disease**;** or [any]

2. An occurrence of a disease above [background or] **its applicable** endemic level[s].

[1. "Endemic level" 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.]

"Pan-non-susceptible organism" means an organism that is resistant or not susceptible to all antimicrobial drugs that a laboratory introduces to the organism to assess antimicrobial susceptibility.

"Parent" means:

1. A biological parent;

2. An adoptive parent;

3. A "resource family parent" as N.J.S.A. 30:4C-26.4 defines that term; and

4. A person or an entity serving as guardian of the person of a minor pursuant to an applicable statute, court rule, court order, or duly executed delegation of parental rights, including a kinship legal guardian pursuant N.J.S.A. 3B:12A-1 et seq.

“Part-time collegian” means a collegian whom an institution of higher education enrolls for the number of credit hours or courses that the institution of higher education categorizes as part-time matriculation.

“Pediatric” means **occurring in** a [person who has not yet attained the age of 18 years] **minor**.

[“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.]

“Pharmacist” means “pharmacist” as N.J.S.A. 45:14-41 defines that term.

“Point-of-care test” or “POC test” means a diagnostic test performed at or near the place at which a specimen is collected that provides results within minutes, such as at the office of a healthcare professional, a pharmacy, or a school.

“Polymerase chain reaction” or “PCR” means a type of nucleic acid amplification test that is used to make multiple copies of a segment of DNA.

“Practice management vendor” means a company that develops and sells electronic information technology applications or software primarily relating to patient medical recordkeeping.

"Precaution" means a precaution as the term is described at CDC and National Center for Immunization and Respiratory Diseases, *General Best Practices for Immunization* (General Best Practices), incorporated herein by reference, as amended and supplemented, available at https://www.cdc.gov/vaccines/hcp/imz-best-practices/index.html..

"PSAST" means Clinical and Laboratory Standards Institute (CLSI), *CLSI M100™ Performance Standards for Antimicrobial Susceptibility Testing, 35th edition* (2025), available at https://clsi.org., specifically https://clsi.org/shop/standards/m100, incorporated herein by reference, as amended and supplemented.

"Public Health and Environmental Laboratories" or "PHEL" means the Public Health and Environmental Laboratories of the of the Public Health Services Branch of the Department, for which the telephone number during business hours is (609) 406-6860 and after business hours is (609) 392-2020, website: https://www.nj.gov/health/phel, and for which the delivery addresses are:

1. For regular mail deliveries:

Public Health and Environmental Laboratories

NJ Department of Health

PO Box 361

Trenton, NJ 08625-0361

2. For specimen deliveries:

Specimen Receiving

Public Health and Environmental Laboratories

NJ Department of Health

3 Schwarzkopf Drive

Ewing, NJ 08628"Public health emergency" [shall have the meaning established at] **means "public health emergency" as** N.J.S.A. 26:13-2 **defines that term**.

"Pupil" or "student" means a minor enrolled in, or attending, any school in the State.

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"Quarantine" [shall have the meaning established at] **means quarantine as** N.J.S.A. **26:4-1 et seq., and** 26:13-[2]**1 et seq., define and describe that term**.

"Rabies post-exposure prophylaxis administration" or "rabies PEP administration" means the administration of rabies immune globulin and/or rabies vaccine to persons exposed and/or potentially exposed to the rabies virus to prevent infection.

"Referral laboratory" means a laboratory that receives a specimen from another laboratory and that performs one or more tests on such specimen.

"Registrant" means a person as to whom the NJIIS contains a record of the person's demographic, immunization, or preventive health screening information.

"Religious-affiliated facility" means a self-identified association of a school or child care center with:

1. A religion, denomination, church, or faith;

2. Religious or spiritual beliefs and practices; or

3. A religious group.

"RNA" means ribonucleic acid.

"SARS" means sudden acute respiratory syndrome.

"Satellite emergency department" means "satellite emergency department" as N.J.A.C. 8:43G-36.2 defines that term.

…

"Serologic test" means a laboratory test performed on blood specimens to measure antibodies and other immunological properties.

"Sexually transmitted disease" means **infection with** syphilis, gonorrhea, chancroid, lymphogranuloma venereum, granuloma inguinale [and chlamydial genital infections]**, or *Chlamydia trachomatis***.

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

"Site administrator" means the person at an NJIIS site who undertakes onsite coordination and oversight of the site's access to and use of the NJIIS and who holds authorization to accept official notices regarding the NJIIS.

"SNOMED" means National Library of Medicine, National Institutes of Health, United States Department of Health and Human Services, *Systematized Nomenclature of Medicine—Clinical Terms (SNOMED-CT) United States (US) Edition*, Version 20250301 (March 2025), incorporated herein by reference, as amended and supplemented available at https://www.nlm.nih.gov/healthit/snomedct/us_edition.html.

"Surveillance case definition" means CDC, *Surveillance Case Definitions for Current and Historical Conditions* (April 12, 2024), incorporated herein by

reference, as amended and supplemented, available at https://ndc.services.cdc.gov

"Vaccine" means an agent that is:

1. Composed of substances derived and/or manufactured from a biologic; and

2. Administered to persons to evoke an immune response to prevent illnesses associated with one or more specific pathogens.

"Valid dose" means a dose of a vaccination that, in accordance with, as applicable, N.J.A.C. 8:57-4, N.J.A.C. 8:57-6, and the ACIP recommendations:

1. Is age-appropriate for the recipient when the recipient receives the dose; and

2. Is spaced appropriately following a prior dose administered to the recipient.

"Vaccine-Preventable Disease Program" or "VPDP" means the program within the Department that is responsible for administering and overseeing the operations of the NJIIS , and for which the mailing address is Vaccine-Preventable Disease Program, NJ Department of Health, PO Box 369, Trenton, NJ 08625-0369, the telephone number during business hours is (609) 826-4861, and the website is https://www.nj.gov/health/cd/vpdp.shtml.

"[Vancomycin-intermediate *Staphylococcus aureus* (VISA)" and] "Vancomycin-resistant *Staphylococcus aureus* [(]**" or "**VRSA[)]" means 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)] **in accordance with PSAST**.

"Veterinarian" [shall mean] **means** a person [licensed by] **whom** the State Board of Veterinary Medical Examiners **licenses** to engage in the practice of veterinary medicine, surgery**,** and dentistry, pursuant to [N.J.A.C. 13:44] **N.J.S.A. 45:16-1 et seq**.

"Veterinary diagnostic laboratory" means a facility used for the performance of chemical, bacteriologic, virologic, parasitologic, serologic, hematologic, immunohematologic, biophysical, cytologic, or other examinations of materials derived from animals for the purpose of yielding information for the diagnosis, prevention, or treatment of disease, or the assessment of medical condition in animals.

"Veterinary diagnostic laboratory director" means a person who is responsible for the administration of the technical and scientific operation of a veterinary diagnostic laboratory, including, but not limited to, supervision of testing procedures and result reporting.

"Virtual private network" or "VPN" means a method to provide secure access to a remote computer over the internet employing encryption.

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

8:57-1.3 (Reserved)

REPEAL: 8:57-1.12 Medical examination and specimen submission

8:57-[1.15]**1.4 Enforcement**

(a) A [physician] **person or entity whom this chapter obliges, and** who fails **or refuses,** to report pursuant to [the requirements of this subchapter shall be]**, or otherwise comply with, this chapter is** subject to [a] fine**s** [as set forth at] **pursuant to applicable laws, including** N.J.S.A. **26:1A-10,** 26:4-129 and 130, [or 26:1A-10] **and may be subject to disciplinary or enforcement measures in accordance with applicable laws and standards of credentialing bodies and other entities with jurisdiction**.

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

[2.]

(b) The Department may [also] report the [physician's] failure to comply with [the provisions of] this [subchapter] **chapter** 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 applicable]

1. Applicable professional board**s** and/or regulatory [agency.

(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 130, or 26:1A-10.

(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 130, or 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, 42.41, and 42.43.

(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 130, or 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 130, or 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 childcare 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 130, or 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.] **agencies that have licensing or credentialing jurisdiction over the noncompliant person or entity; and**

2. Applicable Department programs with jurisdiction over a noncompliant person or entity, including a health care facility, a health care facility administrator, an inpatient or outpatient substance use disorders facility, a State psychiatric hospital as that term is defined at N.J.S.A. 30:1-7 and 4-3.23, a clinical laboratory, a clinical laboratory director, a health officer, a youth camp, a youth camp administrator, an animal control officer, an animal facility, and/or an animal facility manager.

8:57-[4.24]**1.5** [Penalties] **State Sanitary Code; penalties**

(a) This chapter is part of the State Sanitary Code.

(b) Each violation of this [subchapter shall be] **chapter is** subject to [the penalty set forth at] **penalties and sanctions in accordance with applicable law, including, but not limited to,** N.J.S.A. 26:1A-10**, 26:4-129, 26:4-137, and other applicable laws**.

8:57-1.6 (Reserved)

8:57-[1.14]**1.7** Confidentiality

(a) [The] **A record and/or** report[s made] **that the Department and/or a local health agency makes, maintains, receives, or files** pursuant to this [subchapter] **chapter** shall be used only by the local health [department] **agency**, the Department, and [such] other [agencies as] **entities the Commissioner** may [be designated by the Commissioner] **designate in accordance with applicable law and/or** to carry out mandated duties, including the duty to control and suppress communicable infectious diseases.

[(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)] **(b)** The [reports submitted to] **Department may release personally identifiable information obtained pursuant to this chapter:**

1. Unless restricted or prohibited by State or Federal law, for research, as defined by 45 CFR Part 46, Protection of Human Subjects, at 45 CFR § 46.102, Definitions for purposes of this policy, through the Integrated Population Health Data ("iPHD") Project established pursuant to N.J.S.A. 30:4D-65 et seq.;

2. With written consent of the person identified;

3. When the Commissioner determines that disclosure is necessary to enforce public health laws or protect the life or health of one or more persons in accordance with applicable State and Federal laws;

4. To provide information to a Federal or another state public health authority when needed to comply with Federal reporting requirements or to coordinate public health investigations across jurisdictions;

5. To provide information to an individual's health care professional; or

6. Pursuant to the order of a court of competent jurisdiction.

(c) A record and/or report that the Department **or a local health agency makes, maintains, receives, or files, including isolation and/or quarantine orders, material containing the health information of individuals who participate in medical testing, treatment, vaccination, isolation, or quarantine, and any correspondence, records, reports, and other material associated with medical testing, treatment, vaccination, isolation, or quarantine** pursuant to [N.J.A.C. 8:57-1, except for the reports submitted pursuant to N.J.A.C. 8:57-1.8,] **this chapter that contains** demographic and medical information related to [the Department's] **public health** investigations and epidemiological studies of communicable diseases**, infections, and conditions** [and shall] **are** 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] **are deemed, not by way of limitation and subject to any other applicable exemption from disclosure**, **to be**:

1.-3. (No change.)

(d) [Medical] **The Department may use health, medical,** or epidemiologic information collected pursuant to this [subchapter may be disclosed] **chapter** in statistical or other [form] **reports that the Department may elect to issue**, which [does] **do** not disclose the identity of any person.

(e) Regardless of the deletion or redaction of personal identifiers therefrom, a record that the Department or a local health agency holds pursuant to this chapter that might be subject to public access and disclosure within the meaning of N.J.S.A. 47:1A-1 et seq., is not subject thereto if the agency has actual knowledge, or reason to believe, that the remaining unredacted information could be used, alone or in combination with other publicly accessible information, to identify an individual who is the subject of the record or link an individual to the information contained in the record.

(f) Absent the order of a court of competent jurisdiction finding the need to provide access to avert a clear danger to an individual or to public health, access to isolation and/or quarantine orders and the health information of individuals who participate in medical testing, treatment, vaccination, isolation, or quarantine pursuant to this chapter is limited to persons having a legitimate need to acquire or use the information to:

1. Provide treatment to the individual who is the subject of the order or the health information, as applicable;

2. Conduct epidemiologic investigation

3. Investigate the causes of the transmission;

4. Assist law enforcement agencies in identification and location activities; or

5. Facilitate payment by a responsible party for treatment or services rendered.

(g) Subsections (a) through (f) above do not apply with respect to reports and records relating to diseases in animals made pursuant to N.J.A.C. 8:57-2.7 unless information in the record could be used alone or in combination with other information to identify information about an individual that:

1. Is health information or other information about which the individual may have a reasonable expectation of privacy; and/or

2. The agency is required or authorized to protect from public access or disclosure.

(h) Subject to subsection (i) below, to prevent, control, and/or contain the spread of disease and/or an outbreak or a suspected outbreak, the Department may release records and/or information about the medical testing, treatment, vaccination, isolation, or quarantine of a person to:

1. The person's employer;

2. The person who is the subject of the record, upon request;

3. Healthcare personnel;

4. A person who is employed by a food establishment at which a case is employed or attends;

5. A school health official; or

6. An institutional liaison for an institution of higher education.

(i) As a condition of release of information and records pursuant to subsection (h) above, the Commissioner must determine that:

1. The release is necessary to enable the [manager] **administrator** of a place that [the] **an** ill or potentially ill person attends, to protect the health and well-being of the potentially ill person, other persons at the place, and the public; and

2. No alternative to release would reliably protect public health, such as if the Commissioner were to determine that a person refuses and/or is unlikely to comply with a directive to refrain from engaging in work or educational activities that can spread disease, in accordance with a prohibition issued pursuant to N.J.A.C. 8:57-2.12.

8:57-1.8 Department procedure for the establishment of vaccine-preventable disease immunization recommendations and requirements

(a) The Department may identify a vaccine-preventable disease for which:

1. There are no applicable ACIP recommendations;

2. The ACIP recommendations are insufficient to protect the health and safety, or inapposite to the needs, of the people of New Jersey; or

3. The ACIP recommendations lack scientific validity and merit as standards upon which the Department should rely in establishing immunization recommendations and requirements for vaccine-preventable diseases.

(b) In the circumstances described in subsection (a) above, the Department shall evaluate whether the ACIP recommendations for the immunization of all populations of the State against vaccine-preventable disease are sufficient to

ensure the required high levels of immunization that are necessary to protect the people of New Jersey and, in particular, attendees at child care centers, schools, and IHEs, from vaccine-preventable diseases, upon consideration of:

1. Evidence-based best practices and guidance materials issued by nationally recognized advisory and advocacy bodies with respect to preventive health, pediatric, internal, and family medicine services, such as the American Academy of Pediatrics, the American College of Physicians®, the American Academy of Family Physicians, and the American College of Obstetricians and Gynecologists; and/or

2. Vaccine-preventable disease epidemiology, and State and region-specific characteristics, such as population density and demographics.

(c) Upon conclusion of the evaluation described in subsection (b), above, the Department may promulgate rulemaking in accordance with the Administrative Procedure Act, N.J.S.A. 52:14B-1 et seq., notwithstanding the ACIP recommendations:

1. Specifying the types of vaccine-preventable disease immunizations, and/or the number or scheduling of vaccine doses, required for admission to and attendance at child care centers, schools, and IHEs; and/or

2. Specifying the types of vaccine-preventable disease immunizations, and/or the number or scheduling of vaccine doses, recommended for populations of the State, within the meaning of N.J.S.A. 17:48-6i and 6m, 17:48A-7h, 17:48E-35.6 and 35.10, 17B:26-2.1h, 17B:27-46.1h and 46.1*l*, 17B:27A-7 and 19, and 26:2J-4.6.

SUBCHAPTER 2. [(RESERVED)] **REPORTABLE COMMUNICABLE DISEASES, INFECTIONS, AND CONDITIONS**

8:57-2.1 Scope

(a) This subchapter establishes standards applicable to:

1. An administrator;

2. An animal facility manager;

3. A certified animal control officer;

4. A clinical laboratory director;

5. An employer, and/or other person in charge, at a food establishment, drug establishment, and/or cosmetic establishment;

6. A healthcare professional;

7. A health officer;

8. A veterinarian; and

9. A veterinary diagnostic laboratory director.

8:57-[1.4]**2.2** [Health care provider] **Healthcare professional** and administrator reporting [of] **and compliance obligations with respect to** reportable communicable diseases**, infections, and conditions**

(a) Every [health care provider] **healthcare professional** and administrator shall report [any person who is ill or infected] **in accordance with N.J.A.C. 8:57-2.4:**

1. Each case of suspected or confirmed illness with [any] **a reportable** disease**, infection, or condition** listed in N.J.A.C. 8:57-[1.5]**2.3(a)** within the [required

timeframe, and shall make a report as set forth in N.J.A.C. 8:57-1.6] **time specified in 2.3(a);**

2. Each case of confirmed illness with a reportable disease, infection, or condition listed in N.J.A.C. 8:57-2.3(b) and (c) within the time specified therein;

3. A positive POC test result for the organisms listed in N.J.A.C. 8:57-2.6; **and**

4. Each confirmed case of a disease, infection, or condition not listed at N.J.A.C. 8:57-2.3, if the disease, infection, or condition is included on the Notifiable Condition List of infectious conditions for the year in which the disease, infection, or condition is identified, in accordance with N.J.A.C. 8:57-2.3(b).

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

[(c) 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]**, but each person or entity upon whom this chapter establishes reporting obligations, with respect to a case and/or a point-of-care laboratory test result, retains responsibility to ensure that the case and/or the result is reported in accordance with this subchapter, regardless of any understanding or agreement among reporting entities with respect to the delegation of ministerial reporting tasks when entities have mutual case-reporting responsibility**.

(c) A healthcare professional and an administrator shall comply with infection control measures for an individually identified case that the Department or a health officer issues in writing.

8:57-[1.5]**2.3** Reportable communicable diseases**, infections, and conditions**

(a) [Health care providers and administrators shall immediately report by telephone as set forth at N.J.A.C. 8:57-1.6 confirmed] **Confirmed** and suspected cases of **an event listed at subsection (f) below, and** the following**, are immediately** reportable [communicable diseases] **(text in parentheses following a disease, infection, or condition listed below is the causative organism)**:

[1. List of immediately reportable diseases]

…

[Brucellosis *(Brucella spp.)*;]

Biological intoxication, including, but not limited to, intoxication with ricin, abrin, cerberin, and/or harmful algal bloom;

…

Coronavirus, novel, causing severe acute respiratory syndrome, including, but not limited to, SARS, and Middle East respiratory syndrome (commonly referred to as MERS);

…

Foodborne intoxication[s], including, but not limited to, ciguatera, paralytic shellfish poisoning, scombroid, [or] mushroom poisoning**, tetrodotoxin, or *Staphylococcal enterotoxin* B**;

Free-living amebic infection (*Acanthamoeba* species (spp.), *Balamuthia mandrillaris*, *Naegleria fowleri, and Sappinia* spp.);

…

Hantavirus [pulmonary syndrome];

Hepatitis A[, acute];

Influenza **A virus**, novel [strains only] **and/or unsubtypeable**;

…

Melioidosis (*Burkholderia pseudomallei*);

Mpox (*Orthopoxvirus* monkeypox);

…

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

Pertussis, (*Bordetella pertussis*);]

Plague (*Yersinia pestis)*;

Poliomyelitis (poliovirus);

…

[SARS-CoV Disease (SARS);]

Rubella;

…

[Tularemia (*Francisella tularensis*);] and

Viral hemorrhagic fever[s], including, but not limited to, **Chapare, Crimean-Congo hemorrhagic fever,** Ebola, **Guanarito, Junin**, Lassa, [and] **Lujo, Machupo,** Marburg [viruses]**, Rift Valley Fever, and Sabia**.

(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] **Confirmed** cases of the following **are** reportable **by the close of the next business day following the date of confirmation of a** communicable disease[s]**, infection, or condition diagnosis, receipt of a positive laboratory or POC test result, or other confirmation of a communicable disease, infection, or condition**:

[Amoebiasis (*Entamoeba histolytica*);]

Alpha-gal syndrome;

Anaplasmosis *(Anaplasma phagocytophilum);*

Animal bite[s treated for rabies] **of a human**;

Arboviral disease[s]**, including, but not limited to, Bourbon, Cache Valley fever, California serogroup, Heartland, Japanese encephalitis, La Crosse encephalitis, St. Louis encephalitis, and yellow fever virus diseases**;

…

Bacterial tickborne disease, including hard tick relapsing fever (*Borrelia miyamotoi)*;

Brucellosis (*Brucella* spp.);

…

Candida auris* infection or colonization *(Candida auris);

Carbapenemase-producing organism infection or colonization;

…

[Chlamydial infections, sexually transmitted (]*Chlamydia trachomatis* **(electronic case reporting only**);

[Chlamydial conjunctivitis, neonatal (*Chlamydia trachomatis*);]

Chikungunya virus;

…

[Creutzfeldt-Jakob disease;]

COVID-19 infection (SARS-CoV-2);

***Cronobacter* infection (*Cronobacter* spp.), invasive, in minors of up to one year of age;**

…

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

Dengue virus;

Eastern equine encephalitis;

…

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

Extrapulmonary nontuberculous mycobacteria (NTM) infection;

Giardiasis (*Giardia lamblia* **also known as *Giardia intestinalis* and *Giardia duodenalis***);

…

[Hemolytic uremic syndrome, post-diarrheal;]

Hepatitis B, **only if the case:**

1. Is newly diagnosed [acute, perinatal and chronic infections, and pregnant women]**;**

2. Occurs in a person who [have tested]**, while pregnant, tests** positive for [Hepatitis] **hepatitis** B surface antigen**, hepatitis B virus DNA, and/or hepatitis B virus e antigen, regardless of prior diagnosis**;

3. Was originally diagnosed in a jurisdiction or geographic subdivision other than New Jersey; or

4. Occurs in a minor of up to 36 months of age born to a person who had hepatitis B during the minor's gestation and/or birth;

Hepatitis C, [acute and chronic,] **only if the case:**

1. Is newly diagnosed [cases only];

2. Occurs in a person who, while pregnant, tests positive for hepatitis C RNA and/or hepatitis C antigen, regardless of prior diagnosis;

3. Was originally diagnosed in a jurisdiction or geographic subdivision other than New Jersey; or

4. Occurs in a minor of up to 36 months of age born to a person who had hepatitis C during the minor's gestation and/or birth;

…

Influenza (electronic case reporting only);

Jamestown Canyon virus;

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

Leptospirosis (*Leptospira* spp.);

…

Lyme disease (*Borrelia burgdorferi***, electronic case reporting only**);

[Lymphogranuloma venereum (*Chlamydia trachomatis*);]

…

Pertussis (*Bordetella pertussis*);

Powassan virus disease;

…

Q fever (*Coxiella* [*burnetti]* ***burnetii***);

[Rocky Mountain Spotted Fever (*Rickettsia rickettsii*);]

Rabies and rabies PEP administration;

Respiratory syncytial virus (RSV)-associated pediatric mortality;

…

Shigellosis (*Shigella* [*spp.*] **spp.**);

Spotted fever group rickettsiosis (*Rickettsia* spp.);

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

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

Streptococcal disease, invasive group B[, neonatal] **(*Streptococcus agalactiae*) in minors of fewer than 90 days old**;

…

Syphilis, all stages, **including congenital** (*Treponema pallidum*);

[Syphilis, congenital;]

…

Toxic [Shock] **shock** syndrome, [(]other than Streptococcal[)];

Trichinellosis (*Trichinella* [*spiralis*] **spp.**);

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

Tularemia (*Francisella tularensis*);

Typhoid fever (*Salmonella [typhi]* **Typhi**);

Varicella (chickenpox) **(varicella-zoster virus)**;

Vibriosis**, non-cholerae (*Vibrio* spp.)**;

…

[Yellow fever (*Flavivirus*); and

*Yersiniosis (*]

West Nile virus;

Yersiniosis (*Yersinia* [*spp.)*] **spp.); and**

Zika virus.

[(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)] **(c)** [An] **The** 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[,] **collect all MRSA LabID events and submit them to the National Healthcare Safety Network (NHSN)** 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 1,000 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] **in accordance with N.J.A.C. 8:56, Health Care Facility Infection Reporting**.

(d) A suspected or confirmed case of tuberculosis (*Mycobacterium tuberculosis*) is to be reported in accordance with N.J.A.C. 8:57-5, Management of Tuberculosis.

(e) [Reporting of Acquired Immunodeficiency Syndrome (AIDS) and infection with Human Immunodeficiency Virus] **A suspected or confirmed case of human immunodeficiency virus** (HIV) infection [shall] **is to** be **reported** in accordance with N.J.A.C. [8:57-2] **8:65, HIV Infection Reporting.**

(f) Subject to paragraph 2 below:

1. The following are immediately reportable in accordance with subsection (a) above:

i. A suspected or confirmed outbreak of any communicable disease, infection, or condition;

ii. A suspected or confirmed act of bioterrorism; and

iii. Pursuant to N.J.S.A. 26:13-4, a case of a suspected or confirmed disease, infection, or condition that may be reasonably believed to be a potential cause of a public health emergency.

2. A report that subparagraph (f)1iii, above, requires is to be made:

i. By a "health care provider," as N.J.S.A. 26:13-1 et seq., specifically 26:13-2, defines that term; and

ii. To both the Department and the health officer of the municipality in which the case is located.

8:57-[1.6]**2.4** Method of reporting and content of report

(a) [Health care providers and administrators shall] **A** report **of a case that is** immediately [by telephone] **reportable pursuant to N.J.A.C. 8:57-2.3(a) and/or a suspected or confirmed outbreak of any communicable disease, infection or condition, or an act of bioterrorism pursuant to N.J.A.C. 8:57-2.3(f) containing** the information [set forth] at [(c) and] **subsections** (d) **and, if applicable, (e),** below [on confirmed and suspected cases of immediately reportable communicable diseases set forth in N.J.A.C. 8:57-1.5(a) to]**, is to be made by telephone call:**

1. To the health officer of the jurisdiction [where] **in which** the [ill or infected person lives] **case resides**, [or] **but** if **that health officer is unavailable, to the Department;**

2. If the residence of the case is unknown, [wherein] **to the health officer of the jurisdiction in which** the [diagnosis is made, except that health care providers and

administrators shall report ill or infected 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.] **reporting entity is located and at which the case presented, but if that health officer is unavailable, to the Department; and**

[2.] **3.** [Health care providers and administrators](a) **Persons with reporting obligations** 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) [Health care providers and administrators shall] **A** report [by mail or by electronic reporting within 24 hours of diagnosis, the information set forth in (c) below on confirmed] **of a** case[s of] **that is** reportable [communicable diseases set forth in] **pursuant to** N.J.A.C. 8:57-[1.5(b) to]**2.3(b), containing the information specified in subsections (d) and, if applicable, (e), below, is to be made:**

1. By means of telefacsimile or secure email, if the reporting entity is an entity other than those specified in paragraph (b)2, below:

i. Subject to subparagraphs (b)2iii and iv, below, to the health officer of the jurisdiction [where] **in which** the [ill or infected person lives or, if] **case resides;**

ii. Subject to subparagraphs (b)2iii and iv, below, if the residence of the case is unknown, [wherein] **to** the [diagnosis] **health officer of the jurisdiction in which the reporting entity** 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,] **located and in which the case presented; and**

iii. With respect to cases of hepatitis C and tuberculosis, report additionally to the Department; and

iv. With respect to sexually transmitted diseases, report 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]

2. By means of electronic reporting if the reporting entity is:

i. The administrator of a hospital;

ii. A point-of-care test administrator; or

iii. A healthcare professional to whom the Department has provided access to electronic reporting.

3. By means of electronic case reporting if the reporting entity is:

i. A hospital; or

ii. A health care facility that has established a linkage (individually or as part of a larger entity) with the Department to submit electronic case reports.

(c) Persons with reporting obligations may use the Directory of Local Health Departments in New Jersey to locate health officers and local health [departments] **agencies** 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) The disease]

(d) A report [set forth at] **that subsections** (a) and (b) above **and N.J.A.C. 8:57-2.3 require** shall [include] **contain, at minimum**:

1. The name of the disease**, infection, or condition**;

2. The name, age, date of birth, **sex assigned at birth, current** gender **identity, sexual orientation**, race, ethnicity, home address**,** and **all known** telephone number**s and email addresses** of the [person who is ill or infected with such disease] **case**;

3. (No change.)

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

5. Clinical laboratory data[, which] **that** support the diagnosis**, if available**;

6. [Any] **A description of provided** treatment [provided (for sexually transmitted diseases only)];

7. The hospitalization and mortality status of the case; and

[7.] **8.** Such other information [as] **that** the Department **or a health officer** requires concerning a specific [disease] **case**, **which may include clinical information and medical records**.

[(d) In addition to the information set forth at (c) above,]

(e) A report of a suspected outbreak [reports] shall [include] **contain, at minimum, the information required in subsection (d) above, and**:

1. The name, [municipality] **address**, and telephone number of the location [where] **at which** the outbreak occurred;

2. The number [ill] **of cases**;

3. A description of symptoms; **and**

4. Pertinent medical history and available diagnostic confirmation[, and

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

[(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.]

(f) Each hospital that has a web-based mechanism by which the Department and a local health agency with jurisdiction can obtain access to the hospital's electronic health records on suspected or confirmed cases or outbreaks shall notify the Department at dhssmu@doh.nj.gov of the mechanism and the procedure by which the Department can obtain access.

8:57-2.5 Clinical laboratory reporting procedures and obligations with respect to reportable laboratory results; establishment of electronic interface for ELR

(a) Unless N.J.A.C. 8:57-2.6 requires reporting of an organism or result by telephone or another means, clinical laboratories that are to report results to the Department pursuant to N.J.A.C. 8:57-2.6 shall report by means of ELR or electronic reporting.

(b) To establish an ELR interface between the CDRSS Electronic Laboratory Reporting System and a clinical laboratory's electronic system, a clinical laboratory director shall adhere to the ELR On-Boarding Manual, available at Appendix S.

(c) A clinical laboratory shall submit laboratory test results that are reportable by means of ELR pursuant to N.J.A.C. 8:57-2.6 using the LOINC and SNOMED terminology standards and in accordance with:

1. As a maximum standard, the HL7 Implementation Guide; or

2. As an alternative lesser standard, NJ ELR Implementation Guide.

(d) A clinical laboratory director who sends a laboratory specimen to a referral laboratory for testing that yields a result that is subject to reporting or culture isolate submission pursuant to N.J.A.C. 8:57-2.5 and 2.6, shall:

1. Report, and/or ensure the reporting of reportable laboratory results pursuant to N.J.A.C. 8:57-2.5 and 2.6; and

2. Submit, and/or ensure the submission of, culture isolates pursuant to N.J.A.C. 8:57-2.6.

8:57-[1.7]**2.6** [Reporting of positive] **Reportable** laboratory results [denoting diseases] **for certain organisms; reporting procedures; submission of culture isolates and other test specimens**

(a) A clinical laboratory director shall [immediately] report [by telephone] the information [set forth] at [(c)] **subsection (b)** below [on any positive culture,] **upon obtaining, as indicated in (a)1 through 6 below,** a [positive] culture, **a specimen suspected to contain, and/or laboratory** test [or assay] result [specific for] **indicating** the [following] **presence and, if specified, absence, of a listed** organism[s]**, in the time and manner specified,** to**, as indicated,** the **Department, and/or the applicable** local health [officer] **agency** of the jurisdiction [where] **in which** the [person lives] **person whose specimen is tested resides**, or if **the residence is** unknown, to the local health [officer in whose] **agency of the** jurisdiction in which the [health care provider or health care facility requesting] entity that requested the laboratory [examination] **test** is located**.**

1. A laboratory shall report immediately to the Communicable Disease Service, by telephone to (609) 826-5964 during business hours and (609) 392-2020 outside of business hours, a culture that is suspected to contain the following organisms:

[Arboviruses;]

…

[*Bordetella pertussis;*]

Brucella [*spp.;*] **spp.;**

***Burkholderia mallei*;**

***Burkholderia pseudomallei*;**

***Francisella tularensis*; and**

***Yersinia pestis*.**

2. A laboratory shall report immediately by issuance of telephone notice to the applicable local health agency and by means of electronic reporting, including a laboratory that ordinarily reports by means of ELR, a laboratory result that indicates, or is positive (and, if indicated, negative) for, the presence of the following organisms or antibodies:

***Acanthamoeba* spp.;**

***Bacillus anthracis*;**

***Balamuthia mandrillaris*;**

***Burkholderia pseudomallei*;**

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;]

…

[Hepatitis A, (IgM tests only);]

Influenza **A** virus, novel [strains only] **and/or unsubtypeable**;

[Lassa virus;

Marburg virus;]

***Naegleria fowleri*;**

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

[Polio virus] **Poliovirus**;

…

[Rubella virus;]

SARS-CoV;

Rubeola virus, as follows:

i. Immunoglobulin M (IgM) antibody to rubeola virus and, if performed on the same specimen collection, the result (positive or negative) of an immunoglobulin G (IgG) antibody test;

ii. Detection of rubeola virus RNA; and/or

iii. Identification of rubeola virus in culture;

Variola virus spp.;

Viruses causing viral hemorrhagic fever, such as Ebola, Lassa, and Marburg viruses;

…

[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 (c) below 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 subchapter Appendix A to establish electronic laboratory reporting.

(b) A clinical laboratory director shall report by electronic laboratory reporting, or by electronic reporting, or by mail within 72 hours of obtaining the result the information set forth at (c) below on any positive culture, test, or assay result specific for one of the following organisms to the local health 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 directly to the Department:]

3. A laboratory shall report immediately by means of electronic reporting, including a laboratory that ordinarily reports by means of ELR, a result that is positive, and, if specified below, negative for the following organisms, except that a negative culture or blood smear shall not be reported unless preceded by a positive result for the specified organism:

[Acid fast] **Acid-fast** bacilli;

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

Haemophilus influenzae **isolated from cerebrospinal fluid, blood, or a normally sterile site;**

Hepatitis A virus (commonly referred to as HAV) that is identified using the following tests:

i. Immunoglobulin M (commonly referred to as IgM) antibody to HAV (commonly referred to as anti-HAV);

ii. Nucleic acid amplification test, such as polymerase chain reaction (commonly referred to as PCR) or genotyping for HAV RNA positive; and

iii. If a positive result is obtained from a test listed at subparagraphs i. or ii., above, the results of the following tests, if performed on the same specimen collection used to obtain the positive results:

(1) Alanine transaminase (commonly referred to as ALT or SGPT);

(2) Aspartate aminotransferase (commonly referred to as AST or SGOT); and

(3) Total bilirubin;

Orthopoxvirus monkeypox (positive and negative); and

Rubella virus, as follows:

i. Immunoglobulin M (IgM) antibody to rubella virus and, if performed on the same specimen collection, the IgG test result (positive or negative);

ii. Detection of rubella virus RNA; and

iii. Identification of rubella virus in culture.

4. A laboratory shall report by means of ELR or electronic reporting by the close of the business day next following the date on which the result is obtained,

a result that is positive, and, if specified below, negative, for the following organisms, except that a negative culture or blood smear shall not be reported unless preceded by a positive result for the specified organism:

Alpha-gal;

***Anaplasma* spp. (positive and negative);**

Arboviruses, including, but not limited to Bourbon, Cache Valley, California serogroup, Heartland, Japanese encephalitis, La Crosse encephalitis, St. Louis encephalitis, and yellow fever viruses (positive and negative);

Babesia spp. **(positive and negative)**;

***Bordetella pertussis*;**

Borrelia [*burgdorferi*] **spp.**;

***Brucella* spp. (other than culture, positive and negative);**

…

***Candida auris* (positive and negative);**

Carbapenemase-producing organism (positive and negative);

Chikungunya virus (positive and negative);

Chlamydia psittaci **(positive and negative)**;

…

Coxiella [*burnetti*] ***burnetii* (other than culture, positive and negative);**

***Cronobacter* spp., invasive infection, in a minor of up to one year of age;**

Cryptosporidium [*spp.*] **spp.**;

…

[*Entamoeba histolytica*;]

Dengue virus (positive and negative);

Eastern equine encephalitis virus;

Ehrlichia spp. **(positive and negative)**;

Escherichia coli, [shiga toxin producing] **Shiga toxin-producing** strains (**commonly referred to as** STEC) only **(positive and negative)**;

***Francisella tularensis* (other than culture, positive and negative);**

*Giardia lamblia (***also known as *G. intestinalis* and *G. duodenalis)***;

…

Hepatitis B **virus (commonly referred to as HBV, positive and negative), as follows:**

i. Hepatitis B surface antigen (commonly referred to as HBsAg);

ii. Hepatitis B core antibody (commonly referred to as anti-HBc IgM);

iii. Hepatitis B e-antigen (commonly referred to as HBeAg);

iv. NAAT for HBV DNA (including qualitative, quantitative, and genotype testing); and

v. If a positive result is obtained from a test listed in i. through iv. above, the results of the following tests, if performed on the same specimen collection used to obtain the positive result:

(1) Alanine transaminase (commonly referred to as ALT or SGPT);

(2) Aspartate aminotransferase (commonly referred to as AST or SGOT); and

(3) Total bilirubin;

Hepatitis C **virus (commonly referred to as HCV, positive and negative), as follows:**

i. NAAT for HCV RNA positive (including qualitative, quantitative, or genotype testing);

ii. HCV antigen;

iii. Antibodies to HCV (commonly referred to as anti-HCV, Hepatitis C Ab, or Hepatitis C S/CO); and

iv. If a positive result is obtained from a test listed in i. through iii. above, the results of the following tests, if performed on the same specimen collection used to obtain the positive results:

(1) Alanine transaminase (commonly referred to as ALT or SGPT);

(2) Aspartate aminotransferase (commonly referred to as AST or SGOT); and

(3) Total bilirubin;

Influenza, [all isolates] ([only] for laboratories reporting [electronically, or] by [electronic laboratory reporting] **ELR**) **(positive and negative)**;

Jamestown Canyon virus;

Klebsiella granulomatis **(positive and negative)**;

Legionella [*spp.*] **spp. (positive and negative)**;

***Leptospira* spp. (positive and negative);**

…

Mumps virus**, as follows:**

i. Immunoglobulin M (commonly referred to as IgM) antibody to mumps virus, and, if performed on the same specimen collection, the IgG test result (positive and negative);

ii. Detection of mumps virus RNA; or

iii. Identification of mumps virus in culture;

[*Mycobacterium, atypical*;]

…

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

…

Nontuberculous mycobacteria (NTM);

[Plasmodium] ***Plasmodium*** spp. **(positive and negative)**;

Powassan virus, all lineages (positive and negative)*;*

Respiratory syncytial virus (RSV);

Rickettsia [*rickettsii*] **spp**. **(positive and negative)**;

[Rubeola virus;]

Salmonella [*spp.*] **spp. (positive and negative)**;

***Salmonella enterica* serotype Typhi (positive and negative);**

SARS-CoV-2 (positive and negative);

Shigella [*spp.*] **spp. (positive and negative)**;

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

Streptococcus agalactiae, Group B, [neonatal] **isolated from cerebrospinal fluid, blood, or a normally sterile site**;

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

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

*Treponema pallidum***, including all treponemal tests and non-treponemal tests (for example, rapid plasma reagin), in accordance with the CDC Laboratory Recommendations for Syphilis Testing, and as follows:**

i. When using a traditional testing algorithm, a laboratory shall report all subsequent test results (including positive/reactive, negative/non-reactive, and indeterminate treponemal test results) associated with a positive or reactive non-treponemal test result;

ii. When using a reverse testing algorithm, a laboratory shall report all subsequent test results (including positive/reactive, negative/non-reactive, and indeterminate treponemal and non-treponemal test results), following an initial reactive treponemal test result;

iii. If a treponemal test result is indeterminate, a laboratory shall perform, or refer the specimen to another laboratory for the performance of, a second treponemal test on the same specimen using an alternative treponemal test within 24 hours of obtaining the indeterminate test result, and shall report the results of both tests, regardless of the result of the second treponemal test, whether performed by the same laboratory or a different laboratory;

iv. If a non-treponemal test result is indeterminate, a laboratory shall perform, or refer the specimen to another laboratory for the performance of, a second non-treponemal test on the same specimen using the same or an alternative non-treponemal test within 24 hours of obtaining the indeterminate result, and shall report the result of the second test, regardless of the result, whether performed by the same laboratory or a different laboratory; and

v. When non-treponemal tests are done alone without a treponemal order, and the non-treponemal test is reactive, the laboratory shall confirm with the ordering physician that additional testing is not required and must document the physician's response;

Trichinella [*spiralis*] **spp.**;

[Varicella] **Varicella-zoster** virus (except IgG tests);

Vibrio [*spp.*] **spp. (positive and negative, including *Vibrio cholerae*)**;

[and]

West Nile virus (positive and negative);

Yersinia spp.**; and**

Zika virus (positive and negative).

[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) below 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 subchapter Appendix A, to establish electronic laboratory reporting.

(c) The]

5. A laboratory shall report by the close of the business day next following the day on which the result is obtained by means of ELR or electronic reporting a result that is positive for the presence of a causative organism for an infectious

condition that appears on the Notifiable Condition List of infectious conditions for the year in which the result is obtained.

6. A laboratory shall report HIV in accordance with N.J.A.C. 8:65, HIV Infection Reporting.

(b) A report **pursuant to subsection (a), above, unless otherwise specified,** shall contain [the]**:**

1. The reporting laboratory's name, address, and telephone number; [the]

2. The name, age, date of birth, [gender, race, ethnicity,] home address, and telephone number of the [person tested] **case**;

3. Consistent with N.J.S.A. 45:9-42.46, the **race, ethnicity, sexual orientation, and gender identity of the case;**

4. The test performed; [the]

5. The source or type of specimen tested, the date the specimen was collected, and the date of testing; [the]

6. The test result[s]; [and the health care provider's]

7. The name, address, and telephone number **of the healthcare professional that ordered the test; and**

8. Upon request of a health officer or the Department, with respect to a particular case:

i. The laboratory test result report; and/or

ii. The report of the results of other laboratory tests performed with respect to the case that the laboratory performed prior, and/or performs subsequent, to the test that was the subject of the original report.

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

[(e)] **(c)** A clinical laboratory director shall submit **to PHEL,** 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,] all [microbiologic] culture isolates [obtained from human or food specimens] of the following organisms, **and, if a culture isolate is not available, the specimen obtained from a human that is associated with the identification of, or potentially containing, one of the following organisms**:

***Candida auris*;**

Carbapenemase-producing organisms (commonly referred to as CPO);

Chikungunya virus, IgM-positive;

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

Haemophilus influenzae isolated from cerebrospinal fluid [or]**,** blood**, or a normally sterile site**;

Influenza A virus, novel and/or unsubtypeable;

Influenza virus, severe and fatal pediatric;

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

…

[Multidrug-resistant organisms upon the request of the Department;]

Neisseria meningitidis **isolated from cerebrospinal fluid, blood, or a normally sterile site**;

Nontuberculous mycobacteria (commonly referred to as NTM) excluding *Mycobacterium leprae* and *Mycobacterium gordonae*, when collected from cerebrospinal fluid, blood, or a normally sterile site, excluding lower respiratory tract specimens;

Pan-non-susceptible organisms;

Respiratory syncytial virus (RSV), severe and fatal pediatric;

Salmonella [*spp.*] **spp.**;

Shigella [*spp.*] **spp.**; [and

Vancomycin-intermediate *Staphylcoccus aureus* (VISA) and vancomycin-resistant]

Vancomycin-resistant *Staphylococcus aureus* (VRSA) [from any body site]**;**

***Vibrio* spp. (including *Vibrio cholerae*); and**

West Nile virus, IgM-positive.

[(f)] **(d)** [A] **Upon written request of the Department, 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] **each specimen or culture isolate obtained from a human, food, or other source, associated with an outbreak or a public health investigation**.

[(g) A clinical laboratory director for a clinical laboratory, operated by or located within a hospital licensed under N.J.A.C. 8:43G, performing culture and sensitivity testing on isolates from human specimens shall annually report a cumulative summary of the names of the species identified, the number of isolates tested per species, the names of antimicrobial agents tested and the percentage of microorganisms susceptible to the antimicrobial agents tested in the manner described below:

1. 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);

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

3. Exclude duplicate cultures when compiling these antibiograms; and

4. 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.]

(e) Within 72 hours of collection of a human respiratory specimen, a clinical laboratory director shall submit to PHEL:

i. From June through September of each year, three human respiratory specimens per month that have tested positive for influenza virus, or, if fewer than three are available, all influenza virus-positive specimens; and

ii. From October to May of each year, three human respiratory specimens per month that are tested for influenza virus, regardless of the result obtained, or, if fewer than three are available, all specimens tested for influenza virus.

8:57-[1.8]**2.7** Reporting [of zoonotic diseases and any disease outbreaks in domestic companion animals by] **obligations and procedures applicable to a** veterinarian[s], **a** certified animal control officer[s], [and] **an animal rescue organization, an** animal facility [management] **manager, and a veterinary diagnostic laboratory**

(a) A veterinarian, **a** certified animal control officer[s], **an** animal rescue organization manager[s or manager of an]**,** and **an** animal facility manager[s] shall **submit a** report [any case of a domestic companion animal that is ill or infected with] **in accordance with (e) below, upon the diagnosis of** the following zoonotic diseases[, as set forth in (d) and (e) below] **in a domestic companion animal**:

…

Avian [Chlamydiosis] **chlamydiosis** ([Chlamydophila] ***Chlamydia*** *psittaci*);

[*Brucella canis*;]

…

Canine brucellosis (*Brucella canis*);

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

Glanders (*Burkholderia mallei*);

Illness caused by exposure to harmful algal blooms;

Leishmaniasis ***(Leishmania* spp.)***;*

Leptospirosis **(*Leptospira* spp.);**

Lymphocytic choriomeningitis **(lymphocytic choriomeningitis virus)**;

[*Mycobacterium tuberculosis*;]

Melioidosis (*Burkholderia pseudomallei*);

…

Q Fever (*Coxiella [burnetti]* ***burnetii***);

Salmonellosis (*Salmonella* spp.);

SARS-CoV-2;

Tuberculosis (*Mycobacterium tuberculosis*); and

Tularemia (*Francisella tularensis*).

(b) A veterinarian, **a** certified animal control officer**,** [or manager of] an animal facility **manager, and an animal rescue organization manager** shall **submit a** report **of** an animal [affected with rabies or] **that is** suspected of being [affected] **or confirmed to be infected** with rabies**,** in [the manner set forth at] **accordance with** N.J.A.C. 8:23[-1.2].

(c) A veterinarian, **a** certified animal control officer, [or manager of] an animal facility **manager, and an animal rescue organization manager** shall **submit a** report [any]**, in accordance with (e) below, upon identifying an** outbreak or a suspected outbreak [occurring] of **any disease, infection, or condition** in domestic companion animals [as set forth in (d) and (e) below].

(d) [A] **Subject to paragraph (d)1, below, in accordance with N.J.S.A. 26:4-81, a** veterinarian, **a** certified animal control officer, [or] **an** 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]**, and an animal rescue organization manager who is informed, and/or becomes aware, of a person having been bitten by a dog, a cat, or another animal (including a domestic companion animal, livestock, and wildlife), or otherwise potentially exposed to rabies, shall report** to the health officer having jurisdiction over the locality in which the [animal or animal facility is located] **bitten or exposed person is located, within 12 hours of the occurrence of the bite or the identification of the case, provided:**

1. A report pursuant to subsection (d), above, need not be submitted if the exposed or bitten person is under the care of a healthcare professional.

[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] **A** report **that subsections (a) or (c), above, requires** 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] **be made:**

1. By telephone, electronic mail, or telefacsimile;

2. By the close of the business day next following the date of the suspected or confirmed diagnosis or outbreak identification;

3. To the health officer who has jurisdiction over the locality in which each animal that has the suspected or confirmed diagnosis, or is associated with the suspected or confirmed outbreak, is located; and

4. By submission of a completed Zoonotic Disease Incident Report (provided at Appendix A) or a written report containing the information requested therein.

(f) [Animal] **An animal** facility [staff] **manager immediately** shall [immediately report any suspected zoonotic disease or suspected outbreak of any illness in animals currently or recently housed at that animal facility to] **notify** the veterinarian [responsible for] **who is supervising the program of** disease control **and health care** at that animal

facility**, pursuant to N.J.A.C. 8:23A-1.9, upon the identification of a suspected or confirmed outbreak of any illness in one or more animals then presently or recently housed at that animal facility**.

(g) [A] **Duplicate reporting by a** veterinarian, **a** certified animal control officer [or]**, and an** animal facility manager [may delegate the reporting activities set forth at (d) and (e) above to a member of the staff] **is not necessary**, but [this] **a person upon whom this section establishes reporting obligations retains responsibility to ensure that reporting occurs in accordance with this chapter, regardless of any understanding or agreement with respect to the** delegation [does not relieve the veterinarian, certified animal control officer, or animal facility manager] of [the ultimate] **ministerial reporting tasks among reporting entities having concurrent** reporting responsibility.

(h) The Department shall notify the [Department] **Commissioner** of Environmental Protection or Secretary of Agriculture**, as applicable,** of any report made pursuant to this section[, where the Commissioner suspects or detects conditions] **indicative of a suspected or confirmed reportable zoonotic disease or an outbreak of any disease** that could [potentially] affect animals, plants**,** or crops under the jurisdiction of the Department**s** of Environmental Protection or [Department of] Agriculture.

(i) A laboratory that tests samples from animals shall report to the Department in accordance with (j) below, within one business day of obtaining a laboratory test result that is positive for the presence of the following organisms in a domestic companion animal:

Bacillus anthracis;

Brucella canis;

Burkholderia mallei;

Burkholderia pseudomallei;

Chlamydia psittaci;

***Campylobacter* spp.;**

Coxiella burnetii;

***Escherichia coli*, Shiga toxin-producing strains (STEC) only;**

Francisella tularensis

***Leishmania* spp.;**

***Leptospira* spp.;**

Lymphocytic choriomeningitis virus;

***Mycobacterium tuberculosis*;**

Salmonella* spp.*;

SARS-CoV-2; and

***Yersinia pestis*.**

(j) A report pursuant to subsection (i), above, shall be made by telefacsimile to (609) 826-4874 or secure electronic mail to zoonoticrn@doh.nj.gov, and contain:

1. The reporting laboratory's name, address, and telephone number;

2. The name, age, and species of the animal;

3. The address of the animal owner if the animal is owned, and, if applicable, the animal facility at which the animal is located;

4. The test performed;

5. The source or type of specimen tested, the date the specimen was collected, and the date of testing;

6. The test result; and

7. The name, address, and telephone number of the veterinarian or veterinary clinic that ordered the test.

8:57-[1.9]**2.8** [Reporting of diseases by health] **Health** officer[s] **reporting obligations and procedures**

(a) A health officer who [is notified of the existence] **receives a report** of [any] **a** disease, **an infection,** or [illness listed in] **a condition that is reportable pursuant to** N.J.A.C. 8:57-[1.5]**2.3**(a) [and/or a laboratory report listed in N.J.A.C. 8:57-1.7(a)] **immediately** shall [immediately] notify 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] **and report the case by electronic reporting, except telephone notice is not required for the following: *Haemophilus influenzae*, hepatitis A, mpox, and rubella.**

(b) A health officer who receives a report of a disease, an infection, or a condition that is reportable pursuant to N.J.A.C. 8:57-2.3(b) shall report the case by electronic reporting by the close of the business day next following the date of receipt.

(c) A health officer who receives a report pursuant to N.J.A.C. 8:57-2.3(f) immediately shall notify the Department by telephone.

(d) A health officer who receives a report of a laboratory result that is reportable pursuant to N.J.A.C. 8:57-2.6(a)2 immediately shall report the result to the Department by telephone and, if the reporting laboratory has not already electronically reported the result, electronic reporting.

[(b)] **(e)** A health officer who [is notified of the existence] **receives a report** of [any disease or illness listed in N.J.A.C. 8:57-1.5 or] **a** laboratory [report listed in] **result that is reportable pursuant to** N.J.A.C. 8:57-[1.7]**2.6(a)3** shall[, within 24 hours of receipt of the] report[, forward] the [information to the Department via] **result by** electronic reporting **within 12 hours of receipt of the report, if the reporting laboratory has not already electronically reported the result**.

(f) A health officer who receives a report of a laboratory result that is reportable pursuant to N.J.A.C. 8:57-2.6(a)4 shall report the case by electronic reporting by the close of the business day next following the date of receipt, if the reporting laboratory has not already electronically reported the result.

(g) A health officer who receives a Zoonotic Disease Incident Report (provided at Appendix A) or a report pursuant to N.J.A.C. 8:57-2.7 shall submit the report to the CDS by telefacsimile or electronic mail at zoonoticrn@doh.nj.gov by the close of the business day next following the date of receipt of the report.

[1.]

(h) [If the initial] **A health officer who receives a** report **pursuant to this subchapter that** is incomplete[, the health officer] shall [seek complete] **obtain the** information **needed to complete the report** and shall [provide all available] **submit the supplemental** information [to the Department] **in the manner established at**

subsections (a) through (g), above, as applicable, within five [working] **business** days **of the date of receipt** of [receiving] the [initial] report.

[2. The]

(i) A health officer [may substitute reporting by mail upon approval of] whom this section obliges to report a case **or laboratory result** to the Department [for] by means of electronic reporting, and who is unable to report thereby**,** due to equipment **technical or power** failure or other circumstance[s, which prevent] **that impedes** electronic communication[s with]**, shall notify** the Department **by telephone of the obstacle to electronic reporting and obtain Department instruction as to an alternate means of reporting, which instruction will depend on the nature of the reportable case and the urgency with which response is necessary**.

[(c)] **(j)** A health officer who [is notified] **receives a report** of [the existence of any] **a** disease [or illness listed in]**, infection, or condition that is reportable pursuant to** N.J.A.C. 8:57-[1.5]**2.3 or 2.7, which is known or believed to have been contracted in another jurisdiction or to which persons in another jurisdiction may have been exposed, shall notify the health officer for the jurisdiction in which the case is known or believed to have contracted the disease, infection, or condition, and/or in which persons may have been exposed, pursuant to the reporting schedule at N.J.A.C. 8:57-2.3 or 2.7, as applicable.**

(k) A health officer who receives a report of a laboratory [report listed in] **result that is reportable pursuant to** N.J.A.C. 8:57-[1.7, which is]**2.6 regarding a case who does** not **reside** within that health officer's jurisdiction shall [immediately] notify the health officer in whose jurisdiction the [disease or illness is believed to have been contracted

and the health officer in whose jurisdiction the home address of the ill or affected person is located] **case resides, pursuant to the reporting schedule at N.J.A.C. 8:57-2.6**.

[1.]

(l) If [either of the above health] **a** jurisdiction[s are] **to which a health officer must issue notice pursuant to subsections (g) or (h), above, is** not located in New Jersey, the health officer shall forward [this information] **the required notice** 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].

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

8:57-[1.10]**2.9** Health officer investigations

(a) A health officer[,] **shall conduct an investigation in accordance with this section and the Guidance for Prioritizing Communicable Disease Investigations, provided at Appendix T** upon receiving a report **or notification** of **the existence within the health officer's jurisdiction of:**

1. A confirmed or suspected case of a reportable [communicable] disease**, infection, or condition;** or

2. A confirmed or suspected outbreak[, shall investigate the facts contained in the report] **of any disease, infection, or condition**. [A health officer may use the Control of Communicable Diseases Manual, 18th Edition, which provides guidelines for the characteristics and control of communicable diseases CCDM in conducting an investigation that this section requires.

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.]

[(c)] **(b)** [The] **A** health officer**, in** performing [the] **an** investigation [set forth in] **that subsection** (a)**,** above**, requires, at minimum,** shall:

1. Determine whether a single case [or an outbreak] of a reportable [communicable] disease, **infection, or condition, or an outbreak of any disease, infection, or condition,** exists;

2. Determine the number of cases;

[2.] **3.** Ascertain the source and [spread] **mode of transmission** of the [illness] **disease, infection, or condition**; [and]

i. The Department may collaborate with a health officer to support an investigation, as necessary to ensure timely identification of the source and/or mode of transmission;

[3.] **4.** Determine and implement appropriate control measures**;**

5. Collaborate with the Department with respect to public health notifications, such as the issuance of news releases and correspondence to constituents; and

6. Adhere to special direction that the Department might issue under the circumstances of the case or outbreak with respect to the conduct of the investigation.

[(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 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.

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

2. Reports of investigations of other reportable communicable diseases shall be submitted via electronic reporting, except that sexually transmitted diseases and]

[(e)] **(c)** The Department may require [more than one] **other** health officer**s** to participate in [the] **an** investigation **that this section requires**, [including] **in addition to the health officer of the jurisdiction in which a case resides or an outbreak occurs, provided** the **other** health officers [who] have jurisdiction over **locations**:

1. [The location of transmission of] **At which the** disease**, infection, or condition is known or** suspected **to have been transmitted**;

[2. Areas of residence or occupation of person(s) believed to be ill or infected;]

2. At which a case is employed, maintains an additional residence, and/or conducts other activities;

3. [Sites where such persons] **At which a case** may be located **and/**or receiving care; and**/or**

4. [Other jurisdictions, which the] **That the** Department determines [are appropriate and necessary] **to have a geographic nexus to the investigation**.

[(f)] **(d)** If the Department determines that **either** an outbreak is occurring in more than one jurisdiction, **or additional public health measures are indicated**, the Department shall coordinate the investigation, in conjunction with the affected **local** health [departments] **agencies**, and **State and Federal entities, including, but not limited to,** the Centers for Disease Control and Prevention, as [needed] **appropriate under the circumstances**.

(e) Pursuant to N.J.S.A. 26:1A-7, 26:4-2, and 4-4, and A-9, a health officer shall conduct the investigation that this section requires within the health officer's jurisdiction, including an investigation that involves a State-owned or State-affiliated building or facility.

[(g)] **(f)** [The] **A** health officer shall submit **to the Department** a [summary] **status** report [to the Department within]**, pursuant to subsection (g), below, of the health officer's investigation of each case and/or outbreak occurring within the health officer's jurisdiction, at least every** 30 days [of the completion of each outbreak] **during the pendency of the** 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] **until the completion thereof, and more frequently as the Department might require, depending on the nature of**

the threat to public health that a particular disease, infection, condition or outbreak holds and as necessary to prevent further transmission.

(g) A status report that subsection (f), above, requires shall contain, at minimum:

1. A summary of **the health officer's** findings[, actions]**;**

2. A description of public health actions that the health officer has taken [to control disease, and recommendations] **in response to the case and/or outbreak;**

3. A list of recommendations the health officer has issued to affected parties**;**

4. The number of cases;

5. Line lists; and

6.Copies of inspection reports and/or preliminary findings associated with site visits to locations associated with the public health investigation.

[(h) 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.

(i) 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).]

(h) The Department makes available investigation worksheets for optional use by health officers in conducting investigations of various communicable diseases, infections, and conditions, at https://www.nj.gov/health/cd/topics.

8:57-[1.11]**2.10** Isolation and quarantine for communicable disease**, infection, or condition**

(a) A health officer or the Department, upon receiving a report of a **confirmed or suspected case of a** communicable disease, **infection, or condition,** shall[, by] **issue a** written order[, establish such] **that establishes** isolation **and/**or quarantine measures as medically and epidemiologically necessary to prevent or control the spread of the disease**, infection, or condition, and in accordance with applicable provisions of N.J.S.A. 26:4 and/or 26:13**.

1. A geographic subdivision may elect to enact, in whole or in part, the Model Ordinance for Quarantine and Isolation, provided at Appendix R.

2. Subject to Department consent, an order issued pursuant to this section shall remain in force until terminated by the health officer or the Department.

[1.] **3.** If, in the medical and epidemiologic judgment of the health officer or the Department, it is necessary to hospitalize [the ill person in order] **a case** to provide adequate isolation, a health officer or the Department shall promptly remove, or cause to be removed, [that person] **the case** 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 subchapter 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 subchapter 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 **the** access of [the] persons permitted to come in contact with or visit a [person] **case** who is hospitalized**,** [or] isolated**, or quarantined** pursuant to this section [where] **as** medically or epidemiologically necessary to prevent the spread of [the] disease.

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

[(d)] **(c)** [Any] **A** 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.

(d) A health officer shall establish quarantine, testing, and transport procedures for a pet bird that is infected with, or exposed to, avian chlamydiosis, in the manner set forth at N.J.A.C. 8:23-1.4.

(e) In accordance with N.J.S.A. 26:4-2, a health officer, in consultation with the Department, shall isolate, quarantine, test, and/or transport, a domestic companion animal that is confirmed to be, or suspected of being, infected with, or exposed to, a reportable zoonotic disease, infection, or condition set forth at

N.J.A.C. 8:57-2.7, as necessary under the circumstances to protect public health and prevent further transmission.

REPEAL: N.J.A.C. 8:57-1.12

8:57-[1.13]**2.11** [Foodhandlers ill or infected with communicable diseases] **Work restrictions associated with a food establishment, drug establishment, or cosmetic establishment, and other worksite at which food, drugs, or cosmetics are handled**

(a) A person who works at a food establishment, drug establishment, or cosmetic establishment, or is a food employee, who is confirmed as or suspected of being ill or infected with a communicable disease, infection, or condition shall comply with a directive of the Department or a local health agency with jurisdiction prohibiting the person from working at a food establishment, drug establishment, or cosmetic establishment, or other worksite at which food, drugs, or cosmetics are handled.

[(a)] **(b)** [The] **Pursuant to N.J.S.A. 24:15-10, the** Department or a health officer may prohibit a person [who] **from working in a food establishment, drug establishment, and/or cosmetic establishment, or other worksite at which food, drugs, or cosmetics are handled, if the person** is**, or has come in contact with a person who is, confirmed as, or suspected of, being** ill or infected with a communicable disease, [which may be transmitted] **infection, or condition that is transmissible** through food [from working with food as set forth at N.J.A.C. 8:24-2.2]**, drugs, and/or cosmetics**.

[(b) 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 from working with food as set forth at N.J.A.C. 8:24-2.2.]

(c) [The] **As a condition of the removal of a directive or prohibition issued pursuant to subsection (a) and/or (b), above, the** Department or a health officer may require [a] **the** 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] **subject to the directive and/or prohibition** to submit to a physical examination and/or submit specimens [of blood, bodily discharges, or other specimens] for [the purpose of ascertaining] **laboratory testing to determine** whether [or not] the person is [ill or infected with] **capable of transmission of** a communicable disease**, infection, or condition that is transmissible through food, drugs, and/or cosmetics;**

1. The Department and/or the health officer shall not lift a directive or prohibition issued pursuant to subsections (a) and/or (b), above, unless the person subject to the prohibition is incapable of transmission of a communicable disease, infection, or condition that is transmissible through food, drugs, and/or cosmetics.

(d) The Department or a health officer may prohibit the sale or distribution of food [which]**, drugs, and/or cosmetics that**:

1. [A] **Are manufactured, processed, stored, prepared, and/or served by a** person who is [ill or infected with] **capable of transmission of** a communicable disease, [which may be transmitted] **infection, or condition that is transmissible** through food [has prepared]**, drugs, and/or cosmetics**; or

2. [Is considered] **The Department or a health officer determines** to be a possible [vehicle] **vector or fomite** for **the** spread of disease **or infection**.

(e) Pursuant to N.J.S.A. 24:15-10, the owner, operator, and other person in charge of a food establishment, drug establishment, or cosmetic establishment, or other worksite at which food handling is performed, shall comply with a directive of the Department or a local health agency with jurisdiction prohibiting a person who is capable of transmission of a communicable disease, infection, or condition that is transmissible through food, drugs, and/or cosmetics, from working at the establishment or worksite.

8:57-2.12 School data reporting

(a) A school administrator shall ensure that the school reports the following data into the CDRSS between 12:01 am Tuesday and 5:00 pm Wednesday ("reporting dates"):

1. Student census (total number of enrolled students) as of the Tuesday of the reporting dates;

2. Number of students absent on the Tuesday of the reporting dates;

3. Reason for each student's absence on the Tuesday of the reporting dates; and

4. During the Monday through Sunday of the week preceding the reporting dates, the number of outbreaks of a communicable disease, infection, or condition that were known or suspected to have occurred, and, if an outbreak occurred, the communicable disease, infection, or condition that was known or suspected to have occurred as an outbreak.

8:57-2.13 Nursing home data reporting

(a) A nursing home administrator shall ensure that the nursing home reports the following data on both Monday and Thursday of each week ("reporting dates") through REDCap, the CDRSS, or a successor vendor that the Department designates:

1. The total number of residents and staff as of each reporting date;

2. The total number of residents and staff who received a vaccine in compliance with the ACIP recommendations vaccine schedules for COVID-19, influenza, and respiratory syncytial virus, as of each reporting date;

3. During the Monday through Sunday of the week preceding each reporting date, the number of new cases of a reportable communicable disease, infection, or condition among staff and/or residents; and

4. Whether, during the Monday through Sunday of the week preceding the reporting date, an outbreak of any disease, infection, or condition was known or suspected to have occurred, and, if so, the disease, infection, or condition that was confirmed or suspected to have occurred as an outbreak.

(b) The CDS shall report to the Office of Health Care Facility Survey and Field Operations of the Department the failure of a nursing home to timely report in accordance with this section.

(c) The Department shall issue written and electronic notice to nursing homes if the platform vendor changes.

SUBCHAPTER 3. THE NEW JERSEY IMMUNIZATION INFORMATION SYSTEM (NJIIS)

8:57-3.1 Purpose and scope

(a) The purpose of this subchapter is to[:

1. Implement] **implement** N.J.S.A. 26:4-131 et seq. [(P.L. 2004, c. 138)], the Statewide Immunization Registry Act, which designates [and authorizes] the New Jersey Immunization Information System (NJIIS) as the official Statewide immunization registry**, to be** operated by the Department as the single repository of immunization records and [a repository of] preventive health screening records[;

2. Set forth standards for maintaining confidentiality; and

3. Set forth standards for the establishment, use, and maintenance of the NJIIS].

[(b) The purpose of the NJIIS is to:

1. Aid in coordinating and promoting effective and cost-efficient disease screening, prevention, and control efforts throughout the State;

2. Allow authorized users to have wider access to a registrant's immunization and preventive health screening information to promote health maintenance;

3. Provide a mechanism to facilitate notice to registrants of an upcoming or overdue vaccination; and

4. Assist health authorities in identifying registrants that require immediate vaccination in the event of a vaccine preventable disease outbreak or other health emergency.]

[(c)] **(b)** This subchapter applies to [all authorized] **applicants for NJIIS user and NJIIS site access, and persons serving as NJIIS coordinators, NJIIS sites, NJIIS site administrators, NJIIS** users**,** and **NJIIS** registrants.

REPEAL 8:57-3.2 Incorporated documents

REPEAL: 8:57-3.3 Definitions

8:57-[3.4]**3.2** Confidentiality

(a) The Department shall [keep confidential all NJIIS] **maintain the confidentiality of individually identifiable** information [that individually identifies] **in the NJIIS regarding** a registrant[.]**, subject to the following:**

1. [The] **Pursuant to N.J.S.A. 26:4-134i(8), the** Department**, in disseminating statistical information and supporting commentary,** shall [use information contained in the NJIIS for NJIIS purposes set forth in N.J.S.A. 26:4-131 et seq. and this subchapter, including the identification of areas with low immunization coverage rates or public health planning activities and as such, may] release aggregate[, statistical] or summary data or information [in which] **that does not, and/or cannot be used, alone or in combination with other information to, identify an individual** registrant[s are not, and cannot be, identified];

[2. Providers furnishing services, health care payors, and State or local health officers or agencies may exchange information contained in the NJIIS for purposes directly connected to the administration of the NJIIS;

3. The]

2. Other than with respect to a person who has requested to not participate in the NJIIS pursuant to N.J.S.A. 26:4-134(i)4 and N.J.A.C. 8:57-3.15, the Department may release NJIIS information that individually identifies a registrant [or an NJIIS site to]**:**

i. To a State or Federal law enforcement [agencies or agencies having investigatory] authority[, in cooperation with investigations of fraud or abuse, or as required for] **in connection with a criminal and/or civil law enforcement action;**

ii. For public health purposes; and

iii. As authorized or required by applicable law.

[4.] **3.** The Department may transmit, share**,** or exchange information contained in the NJIIS with [other] out-of-State regional or state immunization registries [as set forth at] **in accordance with** N.J.A.C. 8:57-[3.19(c)]**3.15**.

(b) [All] NJIIS sites and [authorized] **NJIIS** users shall [keep medical and personal] **maintain the confidentiality of** information contained in the NJIIS [confidential] pursuant to the [terms of the] **NJIIS** and User Confidentiality **Statement for Access to the NJIIS and User Confidentiality** Agreement[, available] at [subchapter] Appendix [C] **D** and consistent with **and subject to applicable** State and Federal law **and sanctions contained therein, including N.J.S.A. 26:4-137**.

(c) [Health] **A health** benefits plan[s] may request from the Department the NJIIS immunization record[s] of [their] **a registrant who is its existing or** prior member[s]**, customer,** or [beneficiaries that are registrants] **beneficiary** for the purposes stated at

N.J.S.A. 26:4-134(i)7[, which includes completing mandatory HEDIS® reports or similar quality assurance or accreditation reports] by submitting a written request[, including a list of] **to the VPDP that provides the** name[s] and birthdate[s] of the **existing or** prior member[s]**, customer,** or [beneficiaries to the VPDP mailing address] **beneficiary, or by submitting a mandatory HEDIS® report or a similar quality assurance or accreditation report.**

8:57-[3.5]**3.3** Administration

(a) The [Department's Vaccine Preventable Disease Program is responsible for the administration of] **VPDP administers** the NJIIS.

[1. The VPDP shall ensure that the NJIIS conforms to the 12 technical for immunization registries as outlined in the 2001 Immunization Registry Minimum Functional Standards.]

(b) The VPDP **hereby** designates [the local] **each** MCHC [to coordinate the] **as the NJIIS coordinator within that MCHC's jurisdiction for the purposes of NJIIS site and NJIIS user** enrollment[,] **and** training, and **the conduct of NJIIS** quality assurance [components of the NJIIS, which requires the comparison of] **and auditing activities ("NJIIS coordinator").**

1. An NJIIS coordinator has authority to compare immunization information contained within [the registrant's medical] **registrants' health** record**s** at [the health care provider's] **NJIIS** site**s** to [the immunization] information documented in the NJIIS[, under the supervision of the VPDP].

[1.] **2.** [In the event that] **If** the VPDP designates another [organization] **entity** to [coordinate the enrollment, training, and quality assurance components of the] **serve as an** NJIIS **coordinator**, the VPDP shall provide notice of [such] **the** designation, including [contact information for] the **communication information for the** newly designated [organization, through] **entity using** any of the following methods:

i.-iii. (No change.)

[2.] **3.** [The VPDP-designated organization] **An entity that the VPDP designates as an NJIIS coordinator pursuant to paragraph (a)2, above,** shall have the same role and obligations as [the] **an** MCHC pursuant to this subchapter.

(c) [A list of the MCHC contact persons and] **NJIIS coordinator** [contact] information for the coordinators] is available [by mailing a written] **upon** request to the VPDP [mailing address or] **and** online at the NJIIS webpage.

(d) [The local MCHC offices shall have the responsibility] **An NJIIS coordinator has authority to undertake the following duties** in the enrollment process [to]:

1. [Accept letters of interest from applicants, NJIIS enrollment forms, and user confidentiality agreements] **Administer enrollment applications pursuant to N.J.A.C. 8:57-3.7;**

2. Make enrollment eligibility determinations pursuant to N.J.A.C. 8:57-3.6;

3. Ensure that each applicant executes the User Confidentiality Statement for Access to the NJIIS and User Confidentiality Agreement at Appendix D, and undergoes training pursuant to N.J.A.C. 8:57-[3.8 and review them for completeness, eligibility and consistency between the applicant's stated purposes in becoming an

authorized user and the purposes of]**3.5 and 3.6 before granting access to** the NJIIS [as set forth in N.J.S.A. 26:4-132 and 134 and this subchapter];

4. Specify user permissions and access rights pursuant to N.J.A.C. 8:57-3.6;

[2.] **5.** Provide [the mandatory] NJIIS training [for authorized] **to applicants for NJIIS** user[s as set forth at] **status pursuant to** N.J.A.C. 8:57-[3.8(g)]**3.6**; [and]

[3.] **6.** Issue [a] **NJIIS** user [identification for each authorized user that has completed the] **access credentials; and**

7. Audit NJIIS [training] **user and NJIIS site compliance with the Statement for Access to the NJIIS and User Confidentiality Agreement at Appendix D**.

8:57-[3.6]**3.4** Eligibility to become an [authorized] **NJIIS** user and NJIIS site:

(a) [The] **Each of the** following [persons and] entities [are] **is** eligible to become [authorized] **an NJIIS** user:

1. [Health] **A health** care [providers, primary health care providers, child care] **professional;**

2. A health care facility;

3. A State psychiatric hospital as that term is defined at N.J.S.A. 30:1-7 and 4-3.23;

4. An early childhood center[s,]**;**

5. A school[s, colleges, universities,]**;**

6. An IHE;

7. A health benefits plan[s,]**;**

8. An EHR vendor;

9. An HIE, HIO, and HIN;

10. A billing and practice management vendor[s,]**;**

11. A State **agency that has** public health **and/**or [State] social services [programs,] **functions;**

12. A local health [agencies, the] **agency; and**

13. The Department [and designated agents thereof].

[(b) The Commissioner in his or her discretion may expand the list of persons and entities eligible to become authorized users in (a) above through agency rulemaking, if provision of access to the NJIIS would advance the purposes of the NJIIS as set forth at N.J.S.A. 26:4-132 and 134, and this subchapter.]

8:57-[3.7]**3.5** [Authorized] **NJIIS** user enrollment **eligibility** requirements

(a) To enroll as an NJIIS [authorized] user, an applicant shall:

[1. Agree to use the NJIIS to further the purposes of promoting public health or providing patient care;

2. Submit a completed]

1. Execute the NJIIS User Confidentiality **Statement for Access to the NJIIS and User Confidentiality** Agreement [available] at [subchapter] Appendix [C] **D and submit it** to the [local MCHC office] **NJIIS coordinator with jurisdiction**; [and]

[3.] **2.** Complete [the mandatory] NJIIS training [as set forth at] **pursuant to** N.J.A.C. 8:57-[3.8(g)]**3.6; and**

3. Be associated with an approved NJIIS site.

8:57-[3.8]**3.6** [Authorized] **NJIIS site and NJIIS** user applicant enrollment process

(a) [The administrator of any prospective eligible wishing] **An entity seeking** to enroll as an NJIIS site [and as an authorized user] shall submit to the [local] **applicable** [MCHC office, via mail, facsimile or electronic submission,] **NJIIS coordinator with jurisdiction** an application package consisting of:

[1. A statement of interest in enrolling in the NJIIS;]

[2.] **1.** A completed **NJIIS** Enrollment Request for New **NJIIS** Site form[, available] at [subchapter Appendix [A] **B**; [and

3. An original]

2. A fully executed NJIIS User Confidentiality **Statement for Access to the NJIIS and User Confidentiality** Agreement, available] at [subchapter] Appendix [C] **D**, [signed and dated by the responsible person]**; and**

3. A completed NJIIS Interface Enrollment Request form at Appendix U if the entity intends to submit vaccination information to the NJIIS by means of an electronic interface.

(b) [The site administrator of any enrolled site wishing to designate agents to access and utilize the] **To enroll a person as an** NJIIS [shall assist the designated agents in enrolling as authorized] user[s by submitting]**, an NJIIS site administrator shall submit** to the [local MCHC office, via mail, facsimile or electronic submission, an application package consisting of] **applicable NJIIS coordinator with jurisdiction**:

[1. A statement of interest in enrolling in the NJIIS;]

[2.] **1.** A completed **NJIIS** User Enrollment and Training Request form [, available at subchapter Appendix B, through which the administrator shall request the appropriate level of access for the designated agent:

i. “General reader access” means access to view patient information and to run standard reports;

ii. “General user access” means general reader access and access to modify or add information to existing patient records, add new patients, perform inventory, and perform outreach functions to patients for whom the designated agent’s NJIIS site has primary responsibility;

iii. “Site manager access” means general user access and access to modify critical fields, and maintain inventory control records;

iv. “School/college general user access” means general reader access and access to modify or add information to existing student immunization records, add new students, and perform outreach functions to students for whom the designated agent’s NJIIS site has primary responsibility;

v. “School/college general reader access” means access to view student’s information and to run standard reports; or

vi. “VFC data entry access” means access assigned by the New Jersey VFC Program for vaccine accountability] **(provided at Appendix C)**; and

[3.] **2.** A[n original NJIIS] User Confidentiality [Agreement] **Statement for Access to the NJIIS**, available at [subchapter] Appendix [C] **D**, for each designated agent individually signed and dated] **which the prospective NJIIS user has fully executed**.

(c) The [local MCHC offices] **applicable NJIIS coordinator with jurisdiction** shall [enroll or deny] **review an application for NJIIS site** enrollment [of the prospective entity or designated agent as an NJIIS site and authorized user respectively based on:

1. Consistency between the entity's or designated agent's purposes in enrolling as an NJIIS site and an authorized user, respectively, and the purposes of the NJIIS as set forth in N.J.S.A. 26:4-132 and 134 and this subchapter;

2. Whether the entity or designated agent will use the NJIIS to further the purposes of promoting public health or providing patient care;

3. Whether the selected level of] **and, if the NJIIS coordinator determines that the applicant is eligible to become an NJIIS site pursuant to N.J.A.C. 8:57-3.4, grant the application, and allocate the applicable NJIIS access level to the applicant**.

(d) The applicable NJIIS coordinator with jurisdiction shall review an application for NJIIS user enrollment and shall:

1. Grant the application and the requested NJIIS access level if the NJIIS coordinator determines that:

i. The applicant is eligible to be an NJIIS user pursuant to N.J.A.C. 8:57-3.4; and

ii. The requested NJIIS access level is appropriate [as determined by the description of the designated agent's] **to the proposed NJIIS user's** employment functions **as described in the application**;

2. If the application is granted pursuant to paragraph (d)1, above, enroll the NJIIS user; and

[4. Whether the entity or designated agent complies with the eligibility requirements set forth at N.J.A.C. 8:57-3.6]

3. Notify the NJIIS site administrator of the applicant's enrollment as an NJIIS user and that the NJIIS coordinator will issue access credentials upon the NJIIS user's completion of NJIIS training pursuant to subsection (g), below.

[(d)] **(e)** If [the MCHC denies] **an NJIIS coordinator determines to deny an** enrollment [of an entity or designated agent] **application or the requested NJIIS access level**, the [MCHC] **NJIIS site coordinator** shall notify [the]**:**

1. The VPDP of the proposed denial, and the reasons therefor, in writing, within 10 days of the denial determination; and

2. The NJIIS site administrator of the [decision] **denial, and the reasons therefor,** in writing within [30] **20** days [of the date on which the MCHC makes the decision] **after issuing notice pursuant to paragraph (e)1, above**.

[1. The MCHC shall notify the VPDP of all enrollment denials and the reasons thereof, within 10 days of such a decision prior to notifying the administrator.

(e) If the MCHC enrolls an entity as an NJIIS site or a designated agent, the MCHC in conjunction with the Department's Office of Information Technology Services (OITS), shall establish access for the NJIIS site or designated agent and assign a user identification and temporary password that allows each authorized user to have the appropriate level of access described in (b) 2 above, upon confirmation of the successful completion of the mandatory NJIIS training as set forth in (g) below.]

(f) An [administrator or] **NJIIS** site administrator [may] **can** request a change in an [authorized] **NJIIS** user's **NJIIS** access level or password [reset] by submitting a

completed **NJIIS** Request for Change of User Security Authorization/Request for Password Reset form[, available at subchapter Appendix D, to the MCHC at the facsimile number indicated] **in accordance with the instructions** on the form **at Appendix E**.

[1. An authorized user must periodically change his or her password as prompted by the NJIIS.]

(g) [All enrolled authorized] **An NJIIS coordinator shall issue access credentials to an applicant for NJIIS** user[s, shall complete a mandatory] **status whose application is approved when the applicant completes the** NJIIS training [conducted by an NJIIS certified trainer] **that is applicable to the NJIIS user's NJIIS access level**.

[1. Each NJIIS certified trainer shall notify site administrators in writing of authorized users' completion of training.]

1. The schedule of classroom NJIIS training dates and locations, available online NJIIS training resources, and the applicable course registration procedures are on the NJIIS website.

8:57-[3.9]**3.7** [Authorized] **NJIIS** user access to **NJIIS** information **regarding withdrawn registrants; Department investigation of NJIIS system threats; reinstatement of NJIIS user and NJIIS site access**

[(a) Authorized users shall have access to the NJIIS through a web-enabled application after completing the enrollment process set forth at N.J.A.C. 8:57-3.8.

(b) An authorized user will have access to a registrant's NJIIS information limited to the level of access for which the authorized user was approved by the MCHC pursuant to N.J.A.C. 8:57-3.8(b).

(c) Authorized users shall only access information on a registrant contained in the NJIIS under the following circumstances:

1. Health care providers and primary health care providers shall only access information on a registrant whom they have claimed in the NJIIS as their patient and/or to whom they are currently providing health care services;

2. Child care centers, schools, colleges, and universities shall only access immunization information on a registrant that they have enrolled or are in the process of enrolling into their institutions;

3. Health benefits plans shall only access information on a registrant that they have enrolled as a member or beneficiary of their health coverage plan or as set forth at N.J.A.C. 8:57-3.4(c);

4. Billing and practice management vendors shall only access information on a registrant who is the subject of the billing or practice management function the vendor is performing;

5. State public health programs, State or county social services agencies and programs, the collaborating public health programs, NJ Medicaid Program and NJ Family Care Program, shall only access information on a registrant who is enrolled in their specific State public health or State social services agency or program; and

6. Local health officers and agencies or their designees shall only access information on a registrant who resides within the respective local health jurisdiction or

authorized service area for performing and fulfilling their public health functions as they relate to the NJIIS.]

[(d)] **(a)** An [authorized] **NJIIS** user [attempting to obtain access to NJIIS information on a registrant that has withdrawn from the NJIIS] will not [be able to] **have** access [the] **to** information **with respect to a registrant who has withdrawn from the NJIIS pursuant to N.J.A.C. 8:57-3.15,** and**, instead,** will receive a message indicating that [the registrant withdrew from the NJIIS and] the immunization information is not accessible**, hereinafter referred to as an "inactive record**."

[(e)] **(b)** [Anyone] **An NJIIS user** seeking technical information or online assistance may [contact the NJIIS Help Desk at 1-800-883-0059 between 8:00 A.M. and 5:00 P.M., Monday through Friday or by email at helpdesk@doh.state.nj.us] **go to the NJIIS website and select, "Submit a Request," select an NJIIS support topic, and thereupon submit a completed NJIIS Online Ticketing Intake Form at Appendix F.**

(c) Use of the NJIIS by an NJIIS user is subject to audit by the Department and/or the NJIIS coordinator.

(d) Each NJIIS user and NJIIS site is subject to a duty of cooperation with the Department and/or the NJIIS coordinator in the conduct of NJIIS enrollment, training, quality assurance, and auditing activities, and shall provide information and documentation in support of these activities upon request.

(e) The Department may suspend the access of an NJIIS user and/or an NJIIS site at any time if the Department suspects or confirms, and/or to prevent, a threat to data or system security and integrity and, upon conclusion of its investigation of a threat, may prohibit, and/or impose restrictions and conditions on, the

reinstatement of the access of an NJIIS user and/or an NJIIS site to the NJIIS, depending on the result of the investigation and the particular circumstances giving rise to the threat.

8:57-[3.10]**3.8** [Authorized] **Process for NJIIS** user **and NJIIS site** withdrawal**; access level change request**

[(a) Any administrator or] **An NJIIS** site administrator [may withdraw] **can request the withdrawal** or change **of** an [authorized] **NJIIS** user's access to the NJIIS [at any time] by submitting a completed Request for Change of **NJIIS** User Security Authorization/Request for Password Reset form, available at [subchapter] **Chapter** Appendix [D]**E**, to the [NJIIS at the facsimile number indicated on the form] **NJIIS coordinator**.

[(b) The VPDP shall address an administrator's or site administrator's request for withdrawal of an authorized user's NJIIS access within one business day of receipt of the request.]

8:57-[3.11]**3.9** Informing parent[s] **of a newborn about the NJIIS pursuant to N.J.S.A. 26:4-134*i*(3)**

[(a) The VPDP shall make available an NJIIS Informational Brochure, available at subchapter Appendix E.]

[(b)] **(a)** [Birthing facilities] **A birthing facility** shall [complete the following process with regard to informing parents about the NJIIS:

1. Maintain] **maintain** written procedures to document and ensure [each] **that the** parent [is provided a copy of] **of each newborn receives** the NJIIS Informational Brochure before or upon the newborn's discharge from the facility[;

2. Document the parent's receipt of the NJIIS Informational Brochure by making a notation in the newborn's permanent medical record.

3. Provide a Declination of Newborn Automatic Enrollment form, available at subchapter Appendix G, to any parent of a newborn that does not wish to participate in the NJIIS; and

4. Retain a copy of the signed and dated Declination of Newborn Automatic Enrollment form as a part of the permanent medical record of the newborn].

[(c)] **(b)** [Health care providers] **A healthcare professional** providing [medical care] **healthcare** to a [newborn or] minor [born after January 1, 1998,] **who is not enrolled in the NJIIS** shall [complete the following process with regard to informing parents about the NJIIS:

1. Record the provision of] **give either** the NJIIS Informational Brochure**, in a paper or an electronic format, or the link to the brochure on the NJIIS Documents/Forms webpage,** to the **minor's** parent [by documenting the provision of the brochure in the permanent medical record of the newborn or minor;] and

[2. Make a written notation, if the parent declines to participate in the NJIIS, in the permanent medical record of the newborn or] **enroll the** minor **in the NJIIS in accordance with N.J.A.C. 8:57-3.10(d)**.

8:57-[3.12]**3.10** Registrant enrollment

(a) [Birthing facilities] **A birthing facility** shall [automatically] enroll [all] **each** newborn[s born on or after January 1, 1998,] in the NJIIS through submittal of the [electronic birth certificate (]EBC[)] to the [Department's Bureau of Vital Statistics and Registration, unless a parent of a newborn has declined participation and completed a Declination of Newborn Automatic Enrollment form, available in subchapter Appendix G, which shall be noted on the EBC] **Department**.

(b) [When] **In enrolling** a newborn [is enrolled], **a** birthing [facilities] **facility** shall[:

1. Record and report] **record therein** information about any vaccine or biologic [administered at] **that** the birthing facility [on the EBC] **administers to the newborn** prior to [the] discharge [of the newborn; and

2. Submit the EBC to the Department no later than 14 days following the discharge of the newborn].

(c) If the birth of a newborn takes place outside of a birthing facility and the newborn is then transferred to a birthing facility, [it shall be the responsibility of] the receiving birthing facility **shall issue the NJIIS Informational Brochure** to [inform] the parent [about] **pursuant to N.J.A.C. 8:57-3.9(a) and enroll the newborn in** the NJIIS **by means of the EBC**.

(d) [Health care providers] **Subject to paragraph (d)1, below, a health care professional** providing [medical care] **health care services, and a pharmacist who administers an immunization,** to a [newborn or] minor [born after January 1, 1998,] who [was] **is** not [already] enrolled [by a birthing facility] **in the NJIIS** shall

[automatically] enroll the [newborn or] minor in the NJIIS[, unless the parent of the newborn or minor has declined participation].

1. An entity listed in subsection (d) above shall not enroll a minor for whom an inactive record appears in the NJIIS[(e) A parent of a newborn or minor not enrolled by a birthing facility, or a parent of a minor born prior to January 1, 1998, may enroll the newborn or minor in the NJIIS by completing the following process:

1. Make a request for]**.**

(e) An adult person who is not enrolled in the NJIIS can obtain enrollment **in the NJIIS upon request,** to any [authorized] **NJIIS** user[, excluding] **whose user access includes access to record immunizations, other than an NJIIS user that is** a billing vendor, health benefits plan, **read-only user,** or practice management vendor[; or

2. Submit a completed] **by:**

1. Submitting an executed NJIIS Consent to Participate form[, available] at [subchapter] Appendix [F] **G**, to the [VPDP at the VPDP mailing address] **to the NJIIS user, who shall maintain the executed form in the registrant's health record; or**

2. Electronically consenting to participate in the NJIIS by means of an EHR that the NJIIS user maintains if the electronic consent format contains the text of the NJIIS Consent to Participate form at Appendix G.

(f) An [authorized] **NJIIS** user[, as described in (e)1 above, or the VPDP respectively,] shall [enroll]**:**

1. Enroll a [newborn or minor in the NJIIS at the request of his or her parent, or enroll an adult registrant, using the process set forth in (e) above or (g) below, respectively] **person in accordance with a request made pursuant to subsection**

(e), above, by no later than 30 days from the date of the request**;** and [provide the parent, or an adult registrant, with]

2. Give the requester an NJIIS Informational Brochure.

[(g) An adult registrant may enroll in the NJIIS, after receipt of an NJIIS Informational Brochure, available at subchapter Appendix E, by completing the process as set forth at (e)1 or 2 above.]

[1.]

(g) Enrollment in **and/or withdrawal from** the NJIIS [shall] **does** not [diminish the responsibility of] **affect** a [parent or an adult registrant,] **person's obligation** to **provide evidence of immunity or immunization and otherwise** comply with [the immunization rules established at] N.J.A.C. 8:57-4 and 6, as applicable.

[2.]

(h) A registrant who [has previously declined participation in, or withdrawn from] **withdrew from participation in** the NJIIS[, in order to] **pursuant to N.J.A.C. 8:57-3.13 can** resume participation [shall submit a completed Consent] **therein by requesting enrollment and consenting** to [Participate Form, available at subchapter Appendix F to the VPDP mailing address] **participate in accordance with subsection (e), above**.

[(h) A registrant or parent of a registrant, if he or she is a minor, shall not be discriminated against in any way because of his or her refusal to enroll in the NJIIS.

(i) Enrollment in the NJIIS shall not diminish the right of a registrant or his or her parent, if he or she is a minor, to request an exemption from recommended immunizations for medical or religious reasons pursuant to N.J.A.C. 8:57-4.3 and 4.4 or 6.14 and 6.15.]

8:57-[3.13]**3.11** Registrant access to **registrant's NJIIS** information

(a) [Any] **A** registrant or **the** parent of a registrant, if [he or she] **the registrant** is a minor, [shall have access to] **can obtain** a printout of the registrant's NJIIS immunization record[, and may obtain a copy of the record] by [completing the following process]:

1. [Make a written request for record release to] **Requesting the printout from any entity that is** an [authorized] **NJIIS** user[.

i. The authorized user may request verification of identification.

ii. If the authorized user is a health care provider**,** the provider shall keep a copy of the written request for record release in the permanent medical record of the registrant] **whose NJIIS access level includes the ability to view and print the registrant's NJIIS immunization record**; [or]

2. [Submit] **Submitting** a completed **NJIIS** Request for Copy of NJIIS Immunization Record form[available] at [subchapter] Appendix I[,] to the VPDP [at the VPDP mailing address.

(b) The authorized user or the VPDP shall respond to a request for a copy of a registrant's NJIIS immunization record made pursuant to (a) above within 15 days from the date of receipt of the request.]**; or**

3. Obtaining the record from the Docket® mobile phone application or Docket® website application at https://myhealthnj.com, or a successor application administered by an entity with which the Department may elect to enter into a cooperative data sharing agreement.

8:57-[3.14]**3.12** Registrant amendment of **NJIIS** record

(a) [Any] **A** registrant**,** or **the registrant's** parent [of a registrant], if [he or she] **the registrant** is a minor, [may] **can** request [an amendment] **modification and/or supplementation** of [demographic or medical information contained in] the registrant's NJIIS record by submitting a request [for an amendment of:

1. Demographic information] to [an authorized user utilizing] **any of** the **following in the manner the entity to whom the request is made specifies, provided the entity is an NJIIS user:**

i. The registrant's healthcare professional;

ii. A person licensed pursuant to Title 45 of the New Jersey Revised Statutes whose authorized scope of practice includes the ordering of a vaccine, with respect to an amendment request related to a vaccine that the licensee administered; or

iii. A pharmacist, with respect to an amendment request related to a vaccine that the pharmacist administered.

(b) An entity receiving a request for NJIIS record modification or supplementation pursuant to subsection (a) above shall:

1. Annotate the NJIIS record of the person who is the subject of a request made pursuant to this section to indicate the requested modification or supplementation, the determination that the entity makes thereon, if applicable, and any additional information a requester submits in support, and/or in rebuttal to a denial, of a request; and

2. Notify the requester of the opportunity to seek the VPDP's consideration of a denied request.

(c) A registrant, or the registrant's parent if the registrant is a minor can request modification and/or supplementation of the registrant's NJIIS record by submitting a completed NJIIS Request for Change to NJIIS Immunization Record form[, available] at [subchapter] Appendix H[,] **to the VPDP** with [appropriate] documentation [necessary to modify existing information contained in an] **supporting the requested modification and/or supplementation of the** NJIIS record[; or

2. Medical information to the VPDP utilizing the Request for Change to NJIIS Immunization Record form with appropriate documentation necessary to modify existing information contained in an NJIIS record.

i. The VPDP shall process the request for an amendment of medical information in compliance with the Health Insurance Portability and Accountability Act (HIPAA) of 1996, 42 U.S.C. §§ 1301 et seq. and the rules promulgated thereunder by the United States Secretary of Health and Human Services, specifically 45 CFR 164.526].

[(b)] **(d)** The VPDP may deny a request [to amend medical information, upon determining] **made pursuant to subsection (c), above, if it determines** that the [information] **registrant's existing NJIIS record** is accurate [and complete as documented in the NJIIS].

[(c) The authorized user or the VPDP shall respond to the request for an amendment no later than 60 days after receipt of the request.]

(d) If the [authorized user or the] VPDP [grants the requested amendment completely] **determines to grant, in whole** or in part, **a request made pursuant to subsection (c), above,** the [authorized user or] VPDP[, respectively,] shall:

1. [Make the appropriate amendment to] **Modify or supplement** the registrant's [information] **NJIIS record, as appropriate**; and

2. [Inform] **Issue a written notice to** the [registrant of] **requester, indicating** the **VPDP's** acceptance of the request [in accordance with (c) above].

(e) If the [authorized user or] VPDP [denies the requested amendment] **determines to deny, in whole or in part**, **a request made pursuant to subsection (c), above,** the [authorized user or] VPDP[, respectively,] shall [provide the registrant or parent of the registrant, if he or she is a minor, with] **issue** a written [denial pursuant to (c) above that contains the basis] **notice to the requester, indicating the reasons** for **the** denial**,** and [notification] **informing the requester** of the [registrant's] **requester's** right to submit a written statement of reasonable length disagreeing with the denial **to the VPDP for inclusion in the NJIIS record of the registrant who is the subject of the request**.

[(f) If the authorized user or VPDP denies the requested amendment after review of the registrant's or parent of the registrant's written statement pursuant to (e) above, the authorized user or VPDP, respectively, may prepare a written rebuttal to the requestor's statement of disagreement and shall provide a copy of the rebuttal to the requestor.]

[(g)] **(f)** The VPDP shall [make a notation in] **annotate** the [registrant's] NJIIS record [under the NJIIS Notepad tab of the] **of a registrant who is the subject of a** request [for an amendment, the denial of the request, any] **made pursuant to subsection (c), above, to indicate the requested modification or supplementation, the**

determination that the VPDP makes thereon pursuant to subsections (d) and/or (e), above, and, if the requester submits a written statement of disagreement[, and any written] **pursuant to subsection (e), above, the content of the** statement [of rebuttal] **or a summary thereof**.

(h) [The authorized] **An NJIIS** user [or] **and the** VPDP[, respectively,] shall maintain all documents related to [the amendment of record process set forth in (a) though (f) above] **a request made pursuant to this section**.

[(i) Any authorized user or health care provider that denies a request for an amendment pursuant to this section shall send a copy of the denial and all related documents to the VPDP at the VPDP mailing address for additional review.

1. The VPDP shall:

i. Evaluate the denial;

ii. Make recommendations to the authorized user; and

iii. Retain all related denial documentation on file.]

8:57-[3.15]**3.13** [Registrant] **NJIIS registrant** withdrawal**; reenrollment**

(a) A registrant or **the registrant's** parent [of a registrant], if [he or she] **the registrant** is a minor, [may] **can** withdraw from the NJIIS [at any time] by [completing the following process:

1. Submit] **submitting** a completed **NJIIS** Registrant Withdrawal from NJIIS form[, available] at [N.J.A.C. 8:57-3] Appendix J[,] to the VPDP [at the VPDP mailing address].

[i.]

1. The VPDP shall retain the [copy of the] **submitted** form on file.

(b) The VPDP shall respond to a request for withdrawal [made by a registrant, or parent of a registrant, if he or she is a minor,] within [three] **five** business days [from] **of** the date of receipt of the request.

1. The VPDP shall [deactivate the complete immunization] **make inactive the registrant's NJIIS** record [within the NJIIS] and send [a] **written** confirmation [letter] to the [registrant, or parent of a registrant, if he or she is a minor stating that the immunization record was deactivated within the NJIIS Registry] **requester**.

(c) A registrant, or **the registrant's** parent [of a registrant], if [he or she] **the registrant** is a minor**,** [may] **can** reenroll [the registrant] in the NJIIS by [completing the process established at] **consenting to participate pursuant to** N.J.A.C. 8:57-[3.12]**3.10**.

8:57-[3.16]**3.14** Mandatory **NJIIS** participation [for health care providers]

(a) [Every health care provider administering vaccines to children less than seven] **Subject to subsection (h), below, a healthcare professional who provides health care services or administers an immunization to a minor, and a pharmacist who administers an immunization to a minor,** shall [register as] **become** an NJIIS site and [authorized] **NJIIS** user and [commence online reporting of vaccinations, prior to December 31, 2011,] **report** in [compliance] **accordance** with **subsections (d) through (f), below, and** this [subchapter] **chapter**.

(b) [Any health care provider that participates in the] **Subject to an applicable earlier NJIIS registration and reporting obligation that subsection (a), above, establishes, and subject to subsection (h), below, a healthcare professional or pharmacist**

who administers an immunization to a person who is 18 years of age and under 19 years of age shall become an NJIIS **site and NJIIS user and report in accordance with subsections (d) through (f), below, and this chapter, by (one year after the effective date of this section).**

(c) Subject to an applicable earlier registration and reporting obligation that subsections (a) or (b), above, establish, and subject to subsection (h), below, each healthcare professional or pharmacist who administers an immunization to a person who is 19 years of age or older shall register as an NJIIS site and NJIIS user and report in accordance with subsections (d) through (f), below, and this chapter, by (545 days after the effective date of this section).

(d) An entity that is subject to subsections (a), (b), or (c), above, shall report [vaccinations of NJIIS registrants through the following ways:

1. Birthing facilities that complete information on the EBC;

2. The collaborating public health programs, NJ Medicaid Program, or NJ FamilyCare Program;

3. An intermediary authorized user with an electronic connection to] the **information required pursuant to subsections (e) and (f), below, within 14 days of the entity's administration of a vaccine:**

1. By manual data entry into the NJIIS[, such as a practice management vendor, or billing management vendor]; or

[4. An authorized user entering data manually for an NJIIS site directly into the NJIIS through an internet connection]

2. Through an EHR vendor, HIO, HIE, or HIN that establishes an NJIIS interface in accordance with N.J.A.C. 8:57-3.15.

[(c) Health care providers shall report to the NJIIS the administration of a vaccine to a child less than seven years of age within 30 days of administration.

(d) Health care providers]

(e) An entity that is subject to subsections (a), (b), or (c), above shall report, update**, correct,** or verify, as applicable, the following [required data fields for the] **with respect to a** registrant [within 30 days of vaccine administration]:

1.-2. (No change.)

3. Ethnicity[/]**;**

4. Race;

[4.] **5.** (No change in text.)

[5. Address;]

6. [Name of responsible party and relationship] **Relationship of enrollee to head of household at address at which enrollee resides**;

7. Full name of head of household at address at which enrollee resides;

8. Address at which enrollee resides and type of address;

9. Telephone number;

10. Birth country;

11. Plurality (whether enrollee was part of a multiple birth), and if plural birth, birth order of enrollee;

12. Vaccines For Children program eligibility and basis;

13. Insurance type and insurance name;

14. If enrollee is born prior to January 1, 1998, consent information pursuant to N.J.S.A. 26:4-134;

15. Dose information for each dose administered, including:

i. Date enrollee received dose;

[7.] **ii.** Name of the **administered** vaccine [administered].

iii. Administration route;

iv. Funding source of the administered vaccine; and

[8.] **v.** [Vaccine lot] **Lot** number, **manufacturer, and expiration date** of the [vaccine] administered[;

9. Funding source of the vaccine administered; and

10. The month, day, and year the health care provider administered the vaccine] **vaccination**.

[(e) A health care provider may delegate the reporting requirement to a designated agent but such delegation shall not relieve the health care provider of the responsibility to report.]

(f) To the extent the information is available, [participating NJIIS health care providers may] **a healthcare professional who is subject to subsections (a), (b), or (c), above, shall** report [the following] to the NJIIS[, in order] to complete [the] **and/or correct a** registrant's [immunization history] **NJIIS record**:

1. Any doses of vaccinations **that the healthcare professional or another entity** previously administered to [the] **a** registrant [by the health care provider] that [may not have been reported to] the **registrant's** NJIIS **record does not fully and**

accurately reflect, Including the information required pursuant to subsection (e), above; [or]

2. Any doses of vaccinations previously administered to the registrant by [a prior health care provider,] **another entity** for which there is documentation **executed by an entity that is subject to subsections (a), (b), or (c) above, or a healthcare professional or pharmacist in another jurisdiction whose authorized scope of practice includes the administration of immunizations**.

(g) [Non-participating NJIIS health care providers may notify the VPDP of a potential] **A healthcare professional to whom subsections (a), (b), or (c), above, do not apply and who does not participate in the NJIIS as an NJIIS site or NJIIS user shall report a known or suspected** error in [the] **an enrolled NJIIS registrant's** NJIIS record, **and,** if **known to** the [health care provider believes any information is inaccurate or false] **healthcare professional, the correct information,** by submitting [a] **an NJIIS** Request for Change to NJIIS Immunization Record form, available] at [subchapter] Appendix H[, to the VPDP [at the VPDP mailing address].

(h) An entity to whom subsections (a), (b), or (c), above, apply need not become an NJIIS site if the entity is an NJIIS user at an existing NJIIS site through which the entity has an NJIIS access level that enables the entity to report in full compliance with subsections (d) through (f), above.

REPEAL: 8:57-3.17 Application of the NJIIS tracking/reminder recall function

REPEAL: 8:57-3.18 Acceptance of NJIIS record as evidence of immunization

8:57-[3.19]**3.15** Data exchange

(a) [Any authorized] **An NJIIS** user reporting vaccinations pursuant to N.J.A.C. 8:57-[3.16]**3.14**, [or performing or reporting preventive health screenings] shall submit all vaccination [and preventive health screening] information to the NJIIS in a secure electronic format [as established by the Department] **pursuant to subsection (b), below**.

1. The Department shall inform [authorized] **an NJIIS** user[s, as described in (a) above,] of the secure electronic file format upon **the NJIIS user's** completion of the enrollment and training process established at N.J.A.C. 8:57-[3.8]**3.10**.

(b) [Health] **An EHR vendor, an HIO or HIE/HIN, a health** benefit**s** plan[s], **a** billing vendor[s], and **a** practice management vendor[s should] **shall** submit all vaccination [and preventive health screening] information to the NJIIS in accordance with the NJIIS [interface file specifications] **Interface implementation Guide**.

[1. The Department's Office of Information Technology Services (OITS) VPDP will distribute NJIIS interface file specifications to authorized users that will be made available on the NJIIS webpage at: http://njiis.nj.gov/njiis/jsp/uploadshots.jsp.

2. Interface file specifications may be requested by calling the NJIIS helpdesk at (800) 883-0059.

3. Data exchange requestors should develop the interface according to format specifications and contact the NJIIS helpdesk at (800) 883-0059 to establish the secure file transfer protocol.]

(c) The Department may permit the transmission, sharing, or exchange of immunization data contained in the NJIIS, in part or in its entirety, with another state or regional immunization registry that is officially recognized by those states or regions, or by the [United States Department of Health and Human Services, Centers for Disease Control and Prevention (]CDC[)], National Center for Immunization and Respiratory Diseases [through voluntary certification as set forth in the IRC,] pursuant to its healthcare oversight function if:

1. (No change.)

2. The NJIIS data is to be exchanged in [good faith in order to further the purposes of promoting public health and/or providing patient care] **accordance with the American Immunization Registry Association, *Public Health Immunization Information System Interjurisdictional Memorandum of Understanding* (AIRA-PHIIS-IMOU), which is available at https://repository.immregistries.org/resource/public-health-iis-interjurisdictional-memorandum-of-understanding-mou**.

[(d) [To the extent that the Department permits the exchange of] **With respect to any** data [contained in] the [NJIIS, the Department's data exchange policies will be are consistent with the minimum required criteria contained in the Implementation Guide for Immunization Data Transactions] **VPDP receives from a state or regional immunization registry outside of the State of New Jersey, the VPDP will adhere to the processes and procedures established in the AIRA-PHIIS-IMOU, to the extent applicable, or, if the AIRA-PHIIS-IMOU is inapplicable, the processes and procedures of the sending entity**.

8:57-[3.20]**3.16** Reports **pursuant to N.J.S.A. 26:4-134(i)8**

(a) [The] **If the** Department [may release summary statistical data and supporting narrative information collected from the] **disseminates statistical information and supporting commentary in a report using data from the** NJIIS, **the report will represent the NJIIS data** in an aggregate form that does not identify [an] individual registrant**s** [or authorized user, to local health agencies or other State public health or State social service agencies].

[(b) The Department shall prepare statistical and narrative reports or related documents as requested by the NJIIS funding agency, the United States Department of Health and Human Services, CDC and as required by the cooperative grant agreement between the Department and the CDC.

(c) Individuals or entities shall not utilize information contained in the NJIIS or reports generated from the NJIIS in a punitive manner against any authorized user.

(d) Individuals or entities shall not utilize information contained in the NJIIS or reports generated from the NJIIS for a pecuniary or profit motive, marketing, or a similar purpose.

(e) Reports and records of registrants including individual level data generated from the NJIIS or with NJIIS data shall not be included under materials available for public inspection pursuant to N.J.S.A. 47:1A-1 et seq., and shall be]

(b) Information contained in the NJIIS is confidential pursuant to N.J.S.A. 26:4-137 and deemed **to be** "information relating to medical history, diagnosis, treatment, or evaluation" within the meaning of Executive Order 26, § 4(b)1 (McGreevey, August 13,

2002)**,** and therefore, not **a** government record[s] subject to public access or inspection within the meaning of N.J.S.A. 47:1A-1 et seq.

REPEAL: 8:57-3.21 Authorized user immunity

8:57-[3.22]**3.17** [Penalties] **Enforcement**

[(a) Any authorized]

An NJIIS user **or NJIIS site** that fails to comply with this subchapter **or the Statewide Immunization Registry Act, N.J.S.A. 26:131 et seq.,** or knowingly enter[s] false information into the NJIIS [shall be] **is** subject to suspension or revocation of access to the NJIIS**, and applicable penalties, including, but not limited to, those described at N.J.S.A. 26:4-137 (establishing improper disclosure of information contained in the NJIIS as a disorderly persons offense) and N.J.A.C. 8:57-1.4**.

[(b) The Department may issue a written notification and warning to a health care provider that fails to complete required reporting of vaccination information pursuant to N.J.A.C. 8:57-3.16, after consideration of the following:

1. Whether the health care provider failed to report within 30 days of administration; and/or

2. Whether the health care provider failed to register as an NJIIS site and authorized user and commence online reporting of vaccinations prior to January 1, 2011.

(c) If a health care provider continues to be deficient in required reporting of vaccination information 30 days after receiving notification and warning from the Department as set forth in (b) above, the Department may impose other actions, such as:

1. Notification of the hospital medical director or administrator violation to the State Board of Medical Examiners or State Board of Nursing, as appropriate; and/or

2. Notification of the violation to the appropriate hospital medical director or administrator.]

REPEAL: 8:57-3.23 Appeals

SUBCHAPTER 4. IMMUNIZATION OF [PUPILS IN SCHOOL] **CHILDREN IN CHILD CARE CENTERS AND SCHOOLS**

8:57-4.1 [Applicability] **Scope**

(a) This subchapter [shall apply] **applies** to [all children attending any public or] **the administrator ("administrator") of one of the following types of facility in New Jersey:**

1. A public or private school[, child care center, nursery school, preschool or kindergarten in New Jersey] **from pre-kindergarten through the 12th grade or a comparable age-level special education program with an unassigned grade ("school"); and**

2. A child care center.

(b) As used in this subchapter, the term, "facility," collectively refers to a school and a child care center.

(c) This subchapter shall not be construed to limit a private entity's ability to exclude persons from attendance, notwithstanding religious exemptions that would otherwise be available to those persons, who do not have:

1. Immunizations that this chapter requires;

2. Immunizations that the Department recommends pursuant to N.J.A.C. 8:57-1.8; and/or

3. Additional immunizations that this chapter does not require but that are consistent with ACIP recommendations including ACIP recommendations with

respect to applicable Catch-up Schedules, medical contraindications of the ACIP recommendations or AAP Red Book, and recognition of serologic immunity.

8:57-4.2 [Proof] **Administrator to require evidence** of immunization **or immunity**

[A principal, director or other person in charge of a school, preschool, or child care facility]

(a) Subject to N.J.A.C. 8:57-4.7 and 4.8, an administrator of a facility shall require a submission on a minor's behalf, as a condition of the minor's admission to and continued enrollment in the facility, of evidence of the minor's:

1. Immunization compliant with N.J.A.C. **8:57-4.3 and 4.4, and N.J.A.C. 6A:32;**

2. Immunity pursuant to N.J.A.C. 8:57-4.5; and

3. If the applicant for admission or enrollment has attained majority, immunization in accordance with applicable Child and Adolescent Immunization Schedule and the Catch-Up Schedule, and the Adult Immunization Recommendation with respect to the MMR, Tdap or TD, VAR, Hep-B, and Men-ACWY.

(b) Subject to subsections (d), (e) and (f), below, and N.J.A.C. 8:57-1.8, with respect to an administrator's review of the timing of doses identified in documentation submitted as evidence pursuant to N.J.A.C. 8:57-4.3 of a minor's immunization pursuant to N.J.A.C. 8:57-4.4, immunity pursuant to N.J.A.C. 8:57-4.5, and medical contraindication pursuant to N.J.A.C. 8:57-4.7, the ACIP recommendations control as to the validity of doses and the determination of

immunization, immunity, and the ACIP recommendations and the AAP Red Book control as to medical contraindications or precautions.

(c) An administrator shall not knowingly admit **to** or retain **at** a facility [any child] **a minor upon** whose [parent or guardian has not submitted acceptable] **behalf** evidence of the [child's] **minor's** immunization[, according to the schedules specified in this subchapter. Exemptions to this requirement are identified at N.J.A.C. 8:57-4.3 and 4.4] **or immunity pursuant to subsection (a), above, is not submitted**.

(d) In accordance with the McKinney-Vento Homeless Assistance Act, 42 U.S.C. §§ 11431-11435, and N.J.A.C. 6A:32, an administrator of a facility shall allow 10 days for the transfer of a minor's immunization record from a previously attended facility that meet the requirements of this subchapter, during which time the administrator shall admit the minor to the facility.

(e) An administrator shall not exclude a minor from attendance at a facility on the grounds that the immunization evidence submitted on the minor's behalf shows that the minor received doses of the following vaccines on dates that are inconsistent with the ACIP recommendations for minimum age and dose intervals if the immunization evidence shows that the minor received one or more doses of that vaccine prior to (the operative date of this amendment):

1. In lieu of compliance with N.J.A.C. 8:57-4.3(a)1:

i. Diphtheria, tetanus, and acellular pertussis vaccine (commonly referred to as DTaP);

ii. Tetanus, diphtheria, and acellular pertussis vaccine (commonly referred to as Tdap); and/or

iii. Tetanus and diphtheria toxoids vaccine (commonly referred to as Td); and

2. In lieu of compliance with N.J.A.C. 8:57-4.3(a)4, poliovirus (commonly referred to as IPV or OPV).

(f) An administrator shall not exclude a minor from attendance at a facility on the grounds that the immunization evidence submitted on the minor's behalf shows that the minor received doses of the following vaccines on dates that are inconsistent with the ACIP recommendations for minimum age and dose intervals if the immunization evidence shows that the minor received one or more doses of that vaccine prior to January 7, 2008:

1. Measles, mumps, and rubella (commonly referred to as MMR);

2. Hepatitis B (commonly referred to as HepB);

3. Pneumococcal conjugate vaccine (commonly referred to as PCV);

4. *Haemophilus influenzae* type B (commonly referred to as Hib); and

5. Varicella (commonly referred to as VAR).

8:57-4.3 Immunizations as to which an administrator shall require evidence

(a) With respect to a minor entering or attending a child care center, and subject to subsection (b), below, an administrator shall require submission of evidence of the minor's immunization with the following vaccines in accordance with the ACIP recommendations, administered by a healthcare professional, a pharmacist, or a healthcare professional or pharmacist in a jurisdiction other than New Jersey

whose licensed scope of practice includes the administration of immunizations, as a condition of the minor's admission to and continued enrollment therein:

1. DTaP;

2. Hib;

3. PCV;

4. Poliovirus (commonly referred to as IPV or OPV);

5. Influenza (commonly referred to as inactivated influenza vaccine (IIV)) or live-attenuated influenza vaccine (commonly referred to as LAIV), subject to subsection (b), below;

6. MMR; and

7. VAR.

(b) Notwithstanding applicable ACIP recommendations with respect to the influenza vaccine, as an alternative to paragraph (a)5, above, an administrator shall admit a minor upon the submission of evidence of the minor's immunization by November 30 of each year with one dose of the applicable influenza vaccine that is formulated for each influenza season as announced by the CDC.

(c) With respect to a minor entering or attending a school, and subject to subsections (d) through (f), below, an administrator shall require the submission evidence of the minor's immunization with the following vaccines in accordance with the ACIP recommendations, and as administered by a healthcare professional, pharmacist, or a healthcare professional or pharmacist in a jurisdiction other than New Jersey whose licensed scope of practice includes the

administration of immunizations, as a condition of the minor's admission to and continued attendance therein:

1. DTaP, Tetanus diphtheria toxoid (commonly referred to as Td), Tdap, or DT;

2. Hep B;

3. IPV or OPV;

4. MMR;

5. VAR; and

6. Meningococcal serogroups A, C, W, Y vaccine (MenACWY).

(d) Notwithstanding the ACIP recommendations with respect to the number of varicella vaccine doses, as an alternative to paragraph (c)5, above, a school administrator shall admit a minor upon the submission of evidence of the minor's immunization with at least one varicella vaccine dose administered in accordance with the ACIP recommendations as to minimum age.

(e) Notwithstanding the ACIP recommendations with respect to the number of doses of Meningococcal serogroups A, C, W, Y vaccine (MenACWY), as an alternative to paragraph (c)6, above, a school administrator shall admit a minor upon the submission of evidence of the minor's immunization with at least one dose of MenACWY vaccine administered in accordance with the ACIP recommendations.

(f) Notwithstanding ACIP recommendations stating that a minor should receive certain doses of the following vaccines during the ages of four through six years of age ("four to six-year dose"), an administrator of a school shall require the

submission of evidence of a minor's immunization with the four to six-year doses of the following vaccines by the earlier of the minor's attendance at either kindergarten or a higher grade, as a condition of the minor's admission to and attendance therein:

1. DTaP;

2. IPV or OPV; and

3. MMR.

8:57-[4.6]**4.4** [Documents accepted as evidence] **Evidence** of immunization

(a) [The following documents shall be accepted] **An administrator shall accept, and maintain as part a minor's immunization record pursuant to N.J.A.C. 8:57-4.6, the types of documentation listed in (b) below** as evidence of a [child's] **minor's** immunization [history provided that the type of immunization and the date when each immunization was administered is listed] **pursuant to N.J.A.C. 8:57-4.2 and 4.3 if, alone or in combination with other items listed in subsection (b), below, the submitted record identifies:**

1. The month, day, and year of administration of each required vaccine dose; or

2. Only the month and year of administration of each required vaccine dose if the totality of the documentation presented enables the administrator to undertake the analysis and make the determination that subsection (c), below, requires.

(b) Subject to subsection (a), above, the following are acceptable forms of evidence of immunization:

1. An official [school] **facility** record [from any school, pre-school, or child care center] indicating compliance with the immunization requirements of this subchapter**, including electronic health records**;

2. A record [from any public] **issued by a governmental** health [TB indicating compliance with the immunization requirements of this subchapter] **authority of the USA**;

3. A [certificate] **record** signed by a [physician licensed to practice medicine or osteopathy, or an advanced practice nurse (certified registered nurse practitioner, or clinical nurse specialist)]**:**

i. Healthcare professional;

ii. Pharmacist;

iii. Other entity licensed pursuant to Title 45 of the Revised Statutes of New Jersey whose authorized scope of practice includes the ordering of a vaccine; or

v. A person who holds a credential in good standing that is equivalent or corresponds to a credential in subparagraphs i, ii, or iii, above, in [any] **a** jurisdiction [of the United States indicating compliance with the immunization requirements of this subchapter] **other than New Jersey, whose authorized scope of practice includes the ordering of vaccines, provided that if the record is in a language other than English, it is accompanied by an English translation consistent with paragraph (a)6 below**; [or]

4. [The] **An** official record [of immunization] from the New Jersey Immunization Information System [indicating compliance with the immunization requirements of this subchapter.

(b) All immunization records submitted by a parent or guardian]**, including a record from the Docket® mobile phone application or Docket® website application at https://myhealthnj.com, or a successor application administered by an entity with which the Department may elect to enter into a cooperative data sharing agreement;**

5. An Official State of New Jersey School Immunization Record; and/or

6. A signed record issued by a foreign governmental agency, provided that if the record is in a language other than English [shall be accompanied by a]**, it is accompanied by an English** translation [sufficient to determine compliance with the immunization requirements of this subchapter.

(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.] **thereof, certified to be true under the penalty of perjury, as follows:**

i. A certification pursuant to paragraph (b)5, above, from any adult is acceptable, provided the certification contains the following statement, and, below the statement, the printed name and signature of the translator, and the date:

"I certify that the translation above faithfully and accurately reproduces in English the closest natural equivalent of the attached document without embellishment, omission, or explanation. I certify that the foregoing statements made by me are true. I am aware that if any of the foregoing statements made by me are willfully false, I am subject to punishment."

(c) An administrator shall evaluate the evidence submitted on a minor's behalf pursuant to this chapter, in consultation with the VPDP as may be necessary under the circumstances, to confirm that:

1. The minor received the immunizations of which this subchapter requires the administrator to confirm that minor's receipt;

2. The required doses were administered by a healthcare professional or a pharmacist; and

3. The dose of each vaccination was a valid dose pursuant to N.J.A.C. 8:57-4.2 and 4.3.

REPEAL AND NEW RULE: 8:57-4.5

8:57-4.5 Evidence of immunity

(a) An administrator shall accept any of the following as evidence of a minor's immunity to a vaccine-preventable disease against which an administrator is to require evidence of immunization pursuant to N.J.A.C. 8:57-4.3, subject to the

ACIP recommendations for scheduling, laboratory testing, and other indicators of immunity:

1. A positive serologic test result indicative of immunity to:

i. Measles;

ii. Mumps;

iii. Rubella;

iv. Varicella; and/or

v. Poliovirus (demonstrated by a positive test result for types one, two, and three);

2. With respect to hepatitis B, a positive:

i. Surface antibody laboratory test result after completion of the ACIP recommendations schedule; or

ii. Surface antigen laboratory test result and/or core antibody test result, indicating infection with hepatitis B virus; and

3. With respect to varicella, a record signed by a healthcare professional stating that the healthcare professional diagnosed or verified that the minor has had varicella (chicken pox).

(b) Pursuant to N.J.S.A. 26:2N-8 through 11, commonly known as "Holly's Law," in lieu of requiring evidence of a minor's immunization with a second dose of vaccine for measles, mumps, and rubella, an administrator shall admit to school a minor upon the submission of documentation of a positive serologic test result, also known as an antibody titer, for measles, mumps, and rubella.

8:57-4.6 Administrator obligations with respect to documentation of compliance and recordkeeping

(a) Subject to subsection (b), below, an administrator shall:

1. Maintain all original documents and evidence submitted on a minor's behalf pursuant to this subchapter in a discrete file ("file") with respect to each minor that an administrator:

i. Enrolls and admits to a facility; and

ii. Excludes from attendance at a facility,

2. Keep the file separate from the minor's educational and medical records; and

3. Make the file available for inspection on request of the local health official with jurisdiction and/or the Department for immunization record auditing and related public health oversight and enforcement activities.

(b) While an administrator may elect to store electronically some or all information that this subchapter requires the administrator to collect and maintain, the administrator's ability to generate documents or lists from that electronically stored information does not obviate the administrator's obligation to maintain the original (paper) documents and evidence pursuant to subsection (a), above.

1. The Department shall treat any documents or lists the administrator generates from electronically stored information to be in supplement to, and not in replacement of, the file containing the original material.

(c) A file that an administrator creates pursuant to subsection (a), above, is a minor's "immunization record," as laws and rules that are under the administration of the New Jersey Department of Education use that term, specifically with respect to access, retention, transfer, and disposal.

1. See the New Jersey Administrative Code Title 6A, Education, Chapter 16, Programs to Support Student Development, Subchapter 2, General Provisions for School Health Services, specifically N.J.A.C. 6A:16-2.4, Required student health records, and Chapter 32, School District Operations, Subchapter 7, Student Records (N.J.A.C. 8:6A:32-7).

REPEAL: 8:57-4.7 Records required

8:57-[4.3]**4.7** [Medical exemptions] **Exemption due to medical contraindication; required documentation; administrator review**

(a) [A child] **An administrator** shall not [be required to have any specific] **require evidence of** immunization[(s) which are] **or immunity pursuant to N.J.A.C. 8:57-4.2 if a particular immunization is medically contraindicated or presents a precaution for a reason that the ACIP recommendations or the AAP Red Book specify as a vaccine contraindication or precaution; or**

(b) [A written statement submitted to the school, preschool, or child care center from] **In support of an exemption pursuant to subsection (a), above, from a particular required immunization, the administrator shall require the submission of a Request for Medical Exemption from Mandatory Immunization (provided at**

Appendix L) executed by a physician [licensed to practice medicine or osteopathy] or an advanced practice nurse [(certified registered nurse practitioner or clinical nurse specialist) in any jurisdiction of the United States indicating that an] **licensed to practice pursuant to Title 45 of the New Jersey Revised Statutes, including a person who holds a credential in good standing in a jurisdiction of the USA that is equivalent or corresponds to a New Jersey licensed physician or advanced practice nurse, that specifies:**

1. The immunization **that** is medically contraindicated **or presents a precaution [**for a specific] **the specific minor;**

2. The period [of time,] **during which the immunization is medically contraindicated or presents a precaution for the minor;** and [the]

3. The medical reason[(s) for the medical contraindication, based upon valid medical reasons enumerated by the Advisory Committee on Immunization Practices (ACIP) of the United States Public Health Service or the American Academy of Pediatrics (AAP) guidelines, will exempt a pupil from the specific immunization requirement for the stated] **for which, and the** period [of time] **during which, administration of the immunization is contraindicated or presents a precaution to the minor.**

[1. The guidelines identified in (b) above are available as follows:

i. Advisory Committee on Immunization Practices, U.S. Public Health Service, Centers for Disease Control and Prevention, Atlanta, GA 30333; and

ii. American Academy of Pediatrics, Committee on Infectious Diseases, PO Box 927, Elk Grove, IL 60009-0927.]

(c) The [physician's or an advanced practice nurse's (certified registered nurse practitioner or clinical nurse specialist) statement] **administrator** shall [be retained]**:**

1. Review the statement submitted pursuant to this section for compliance with subsections (a) and (b), above, in consultation with the VPDP as may be necessary under the circumstances;

2. If the statement complies with subsections (a) and (b), above, review the grant of exemption at least annually or by the end of the contraindication period that the statement specifies pursuant to paragraph (b)2, above, whichever is earlier, to ensure that, upon the conclusion of the contraindication period, evidence of immunization or immunity in accordance with N.J.A.C. 8:57-4.2 and the ACIP recommendations is submitted; and

3. Retain the statement as part of the [child's] immunization record [and shall be reviewed annually by the school, preschool, or child care facility. When the child's medical condition permits immunization, this exemption shall thereupon terminate and the child shall be required to obtain the immunization(s) from which he or she has been exempted] **pursuant to N.J.A.C. 8:57-4.6**.

[(d) Those children with medical exemptions to receiving specific immunizations may be excluded from the school, preschool, or child care facility during a vaccine-preventable disease outbreak or threatened outbreak as determined by the Commissioner, Department of Health and Senior Services or his or her designee.

(e) As provided by N.J.S.A. 26:4-6, "Any body having control of a school may, on account of the prevalence of any communicable disease, or to prevent the spread of communicable diseases, prohibit the attendance of any teacher or pupil of any school

under their control and specify the time during which the teacher or scholar shall remain away from school." The Department of Health and Senior Services shall provide guidance to the school of the appropriateness of any such prohibition. All schools are required to comply with the provisions of N.J.A.C. 8:61-1.1 regarding attendance at school by pupils or adults infected by Human Immunodeficiency Virus (HIV).]

REPEAL: 8:57-4.8 Reports to be sent to Department of Health and Senior Services

8:57-[4.4]**4.8** Religious exemption[s]

(a) [Each school, preschool, or] **Pursuant to N.J.S.A. 26:1A-9.1 and 30:5B-5, the administrator of a** child care center shall [exempt a child from mandatory] **not require evidence of** immunization **or immunity pursuant to N.J.A.C. 8:57-4.2** if the [child's] **minor's** parent [or guardian submits to the school, preschool, or child care center a written, signed statement requesting an exemption, pursuant or parents] **objects thereto** "**upon the ground that the immunization interferes with the free exercise of the pupil's religious rights" and "on the ground that it conflicts with the tenets and practice of a recognized church or religious denomination of which the parent or child is an adherent or member."**

(b) Pursuant to [the requirements for religious exemption established at] N.J.S.A. 26:1A-9.1, [on] **the administrator of a school shall not require evidence of a minor's immunization or immunity pursuant to N.J.A.C. 8:57-4.2** "**if the parent … of the pupil objects thereto upon** the ground that the immunization interferes with the free exercise of the pupil's religious rights."

(c) In support of a request for an exemption pursuant to subsection (a) or (b), above, the administrator of a child care center or school shall require the minor's parent to submit a written statement that includes a date and is signed by hand:

1. Requesting an exemption on the grounds described in subsection (a) or (b), above, as applicable; and

2. If the request is with respect to a particular immunization rather than to all immunizations, specifying the immunization to which the request applies.

(d) An administrator shall not exempt a minor from [exempting a child from mandatory] **the obligation to provide evidence of** immunization **or immunity pursuant to N.J.A.C. 8:57-4.2** on the sole basis of a moral or philosophical objection to immunization.

(e) An administrator shall require evidence of immunization or immunity pursuant to N.J.A.C. 8:57-4.2 with respect to immunizations from which the parent does not request exemption pursuant to this section, which a parent specifies pursuant to paragraph (c)2, above.

[(b)] **(f)** [Religious] **The administrator of a religious**-affiliated [schools or child care centers shall have the authority to] **facility can** withhold or grant a **request for** [religious] exemption [from the required immunizations for pupils entering or attending their institutions] **pursuant to this section** without challenge by any secular health authority.

[(c) Each school, preschool, or child care center]

(g) An administrator shall retain a [copy of the] written statement [set forth in (a)] **that a parent submits pursuant to subsection (c),** above**,** in the [child's] **minor's** immunization record.

[(d) A school, preschool, or child care center may exclude children with religious exemptions from receiving immunizing agents from the school, preschool, or child care center during a vaccine-preventable disease outbreak or threatened outbreak as determined by the Commissioner, Department of Health and Senior Services, or his or her designee.

(e) As provided by N.J.S.A. 26:4-6, "Any body having control of a school may, on account of the prevalence of any communicable disease, or to prevent the spread of communicable diseases, prohibit the attendance of any teacher or pupil of any school under their control and specify the time during which the teacher or scholar shall remain away from school."

1. The Department of Health and Senior Services shall provide guidance to the school on the appropriateness of any such prohibition.

2. All schools are required to comply with the provisions of N.J.A.C. 8:61-2.1 regarding attendance at school by pupils or adults infected by Human Immunodeficiency Virus (HIV).

(f) Those children enrolled in school, preschool, or child care centers before September 1, 1991, and who have previously been granted]

(h) Subject to subsection (i), below, an administrator shall not require the parent of a [religious] **minor to whom the administrator grants an** exemption[, shall not be

required] **pursuant to this section** to reapply **annually** for [a new religious] **the same** exemption [under N.J.A.C. 8:57-4.4(a)].

(i) If a minor, for whom an exemption pursuant to this section is of record, receives, with the consent of the minor's parent, an immunization that contravenes the statement the parent submitted pursuant to subsection (c), above, the administrator shall deem the request for exemption to be withdrawn and thereafter the administrator shall require compliance with N.J.A.C. 8:57-4.2 in accordance the ACIP recommendations and this chapter.

REPEAL AND NEW RULE: 8:57-4.9

8:57-4.9 Provisional and foreign admission

(a) With respect to a minor upon whose behalf evidence pursuant N.J.A.C. 8:57-4.2 showing compliance with applicable immunization schedules in accordance with the ACIP recommendations is not submitted, the administrator of a facility, subject to subsection (b), below, shall neither admit the minor to, nor continue the minor's enrollment at, the facility, unless and until evidence is submitted compliant with N.J.A.C. 8:57-4.4 showing that the minor:

1. Has received at least one dose of each immunization that N.J.A.C. 8:57-4.3 requires; and

2. Is no later than 14 days behind in receiving the remaining doses in accordance with the applicable Catch-up Schedule.

(b) With respect to a minor who is entering, or transferring into, a facility from outside of the USA, upon whose behalf evidence pursuant N.J.A.C. 8:57-4.2 showing compliance with applicable immunization schedules in accordance with the ACIP recommendations is not submitted, an administrator shall admit the minor to the facility for no longer than 30 days, during which evidence on the minor's behalf shall be submitted:

1. Compliant with N.J.A.C. 8:57-4.4 and/or 4.5 of the minor's immunization or immunity; and/or

2. Compliant with N.J.A.C. 8:57-4.4 that the minor:

i. Has received at least one dose of each immunization of which N.J.A.C. 8:57-4.3 requires evidence of immunization in accordance with the ACIP recommendations; and

ii. Is no later than 14 days behind in receiving the remaining doses in accordance with the applicable Catch-up Schedule.

(c) Subject to paragraph (c)1, below, subsection (b), above, applies to persons to whom the Interstate Compact on Educational Opportunity for Military Children applies, pursuant to N.J.S.A. 18A:75A-1 et seq., specifically 18A:75A-4 and 5.

1. Pursuant to N.J.S.A. 18A:75A-19, rules of the Military Interstate Children's Compact Commission (MIC3), promulgated pursuant to N.J.S.A. 18A:75A-13, supersede and preempt subsection (c), above, if the MIC3 rules authorize longer periods within which evidence of a person's immunization or immunity in accordance with the ACIP recommendations is to be submitted, as a condition of a person's admission to or continued attendance at a facility.

2. The MIC3 rules are available from the MIC3, 1776 Avenue of the States, Lexington, KY 40511, telephone: (859) 244-8000, telefacsimile: (859) 244-8001, email: mic3info@csg.org, and website: https://www.mic3.net.

REPEAL AND NEW RULE: 8:57-4.10

8:57-4.10 Exclusion of persons during actual or threatened vaccine-preventable disease outbreak

(a) Notwithstanding the grant of an exemption or provisional admission pursuant to N.J.A.C. 8:57-4.7, 4.8, or 4.9, if the Commissioner determines that an actual or threatened communicable disease outbreak or a public health emergency exists, and at the direction of the Commissioner or the local health agency with jurisdiction, the administrator of a facility shall exclude unimmunized, under-immunized, and provisionally admitted persons from attendance thereat during the actual or suspected communicable disease outbreak or public health emergency.

(b) Pursuant to N.J.S.A. 26:4-6, "Any body having control of a school may, on account of the prevalence of any communicable disease, or to prevent the spread of communicable diseases, prohibit the attendance of any teacher or pupil of any school under their control and specify the time during which the teacher or scholar shall remain away from school."

1. To implement subsection (b), above, the local health agency with jurisdiction or the Department shall determine:

i. The "prevalence" of the communicable disease;

ii. The existence of an epidemiological basis to warrant the prohibition of persons from attendance to prevent the spread of the communicable disease; and

iii. The time and/or circumstances during which the prohibition of persons from attendance is to remain in effect.

(c) The administrator shall maintain a record of persons admitted to a facility pursuant to N.J.A.C. 8:57-4.7, 4.8, and 4.9 and make an up-to-date list of those persons available to the Department and/or the local health agency upon request during a suspected or confirmed communicable disease outbreak and/or a public health emergency.

(d) The administrator of a facility may elect to notify a parent who submits a request for exemption of a minor pursuant to N.J.A.C. 8:57-4.7 and 4.8, or who obtains provisional admission of a minor pursuant to N.J.A.C. 8:57-4.9, of the potential exclusion of the minor from attendance at the facility pursuant to this section during a suspected or confirmed communicable disease outbreak and/or a public health emergency.

REPEAL AND NEW RULE: 8:57-4.11

8:57-4.11 Reports to be sent to the Department and local health agency

(a) The administrator of a facility shall report of the immunization status of the persons attending or enrolled in the facility by submission of the information

required in the Annual Immunization Status Report (provided at Appendix M) in the NJIIS by December 1 of each year.

(b)The Department shall notify applicable State agencies with jurisdiction, such as the New Jersey Departments of Education and Children and Families, and the applicable local health agency with jurisdiction, if an administrator is delinquent in timely compliance with this section.

REPEAL AND NEW RULE: 8:57-4.12

8:57-4.12 Meningitis-Containing Vaccination Immunization Information Fact Sheet established

(a) Pursuant to N.J.S.A. 26:2X-3, the Department establishes the brochure entitled "Meningococcal Disease: Are You Protected?" as the educational fact sheet of which the Commissioner of Education is to establish school district procedures requiring annual dissemination pursuant to N.J.S.A. 18A:40-21.2.

REPEAL AND NEW RULE: 8:57-4.13

8:57-4.13 Immunization of children at public expense authorized

Pursuant to N.J.S.A. 18A:40-20 and 26, and 26:4-8.1, a board of education and/or a local board of health can provide, at public expense, the necessary equipment, materials, and services for immunizing children with immunizing agents in accordance with this subchapter, and other immunizing agents as the

Department may direct or authorize, and/or as the ACIP recommendations may provide.

REPEAL: 8:57-4.14 through 4.21.

8:57-[4.22]**4.14** Emergency powers of the Commissioner[, Department of Health and Senior Services]

(a) [In the event that] **If** the Commissioner[, Department of Health and Senior Services or his or her designee] determines [either] that [an] **a suspected or confirmed** [outbreak or threatened] outbreak of disease [or other public health immunization emergency] exists, **or the Governor declares a public health emergency exists pursuant to N.J.S.A. 26:13,** the Commissioner [or his or her designee] may [issue either] **require** additional immunization**s** [requirements to control the outbreak or threat of an outbreak] or modify **existing** immunization requirements [to meet the emergency] **as a condition of a person's continued admission to or enrollment at a facility**.

(b) [All children] **An administrator shall exclude from a facility any person** failing to meet [these] additional **or modified** requirements [shall be excluded from a school, preschool, or child care center until the outbreak or threatened outbreak is over] **that the Commissioner issues pursuant to subsection (a), above, upon the direction of the local health agency with jurisdiction or the Department, which direction may include the exclusion of unimmunized and under-immunized persons notwithstanding the existence of an otherwise applicable medical contraindication, or religious exemption**.

(c) [These] **Additional or modified** requirements [or amendments to the requirements] **that the Commissioner issues pursuant to subsection (a), above,** shall remain in effect until [such time as] the Commissioner[, Department of Health and Senior Services or his or her designee] determines that [an] **the suspected or confirmed** outbreak[, or a threatened outbreak, no longer exists or the emergency is declared over, or for three months after the declaration of the emergency, whichever one comes first] **or other public health emergency is over, and issues a declaration to this effect that rescinds the additional or modified requirements**. [The Commissioner, Department of Health and Senior Services or his or her designee may redeclare a state of emergency if the emergency has not ended.]

(d) [In the event of] **If the CDC determines that** a national [or State] vaccine supply shortage[, as determined by the Centers for Disease Control and Prevention and Commissioner, respectively,] **or disruption exists or** the Commissioner [or his or her designee] **determines that a vaccine supply shortage or disruption affecting New Jersey exists, the Commissioner** may temporarily suspend [the] **or modify** immunization requirement**s** [for the particular immunization affected by the supply shortage,] after provision of notice to the public[, such as] through any of the methods below:

1.-3. (No change.)

[4. The Department's Vaccine Preventable Disease Program;] or

[5.] **4.** Any other method reasonably calculated to inform those persons most likely to be affected by or interested in the temporary immunization suspension.

REPEAL: 8:57-4.23 Optimal immunization recommendations

RECODIFICATION WITH AMENDMENT: N.J.A.C. 8:57-4.24 PENALTIES AS **NEW 8:57-1.5**; SEE ABOVE)

REPEAL: APPENDIX

SUBCHAPTER 5. MANAGEMENT OF TUBERCULOSIS

8:57-5.1 Purpose and scope

(a) The purpose of this subchapter is [to control the spread of] **manage** tuberculosis **disease (*Mycobacterium tuberculosis*)** (TB) by maximizing the use of currently available and highly effective treatments **and to establish standards for the reporting, diagnosis, and treatment of cases of TB in the least restrictive environment and manner**.

(b) This subchapter applies to [persons who have suspected or confirmed TB disease a]**:**

1. A TB patient [as diagnosed by a health care provider, 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]

2. A TB patient's contact;

3. A Class B1 or B2 referral[s from the Centers for Disease Control and Prevention (CDC)] who [are residing] **resides** in New Jersey[.

(c) Local health]**:**

4. A health officer[s, public health nurse]**;**

5. A [case managers,] **Public Health Nurse Case Manager;**

6. A health care [providers] **professional;** and

7. An administrator[s of hospitals and correctional facilities are primarily responsible for implementation of this subchapter].

[(d)] **(c)** [Local] **This subchapter establishes standards authorizing a** health officer[s in areas where] **for** the [person with suspected or confirmed, infectious or potentially infectious] **jurisdiction in which a person with** TB [disease] resides[, frequents] or receives care [may]**, or that the person frequents, to** take any action authorized under this subchapter [if he or she] **that the health officer** determines [that it is] **to be** necessary to protect the health of the [person] **TB case** or the public.

[(e) The guiding goals underlying this subchapter are:

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

2. To diagnose and treat persons with 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.]

8:57-5.3 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 [(]**" or "**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, and [indicates] **indicate** the likelihood of infectiousness if from a pulmonary source such as, but not limited to, sputum, [bronchioalveolar] **bronchoalveolar** lavage, gastric aspirate, lung tissue, as well as other tissue of the respiratory tract such as the larynx or epiglottis.

…

"Class B1 or B2 referral[s]" means **a** referral[s] from the CDC's Division of Global Migration [and Quarantine] **Health**, which informs the Department of persons who are refugees, parolees, asylees, or recent legal immigrants to the [United States] **USA**, [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. (No change.)

"[Interferon gamma] **Interferon-gamma** release assay" **or "IGRA"** means **a** QuantiFERON®-Gold **Plus** or [T-spot.TB assay] **T-SPOT®.*TB* test**.

"Latent TB infection" means the presence of [Mycobacterium tuberculosis] ***Mycobacterium tuberculosis*** bacteria in the body as evidenced by a significant

reaction to a Mantoux tuberculin skin test or positive [interferon gamma release assay] **IGRA**.

1. A person with latent TB infection [does not have an illness] **is neither ill** nor [is he or she] infectious.

…

"[Multiple drug] **Multidrug-**resistant tuberculosis [(]**" or "**MDR-TB[)]" means a form of TB disease that is resistant to at least isoniazid and rifampin.

…

"Suspected or confirmed infectious or potentially infectious TB disease" means one or more of the following:

1. A [patient with a] smear **that is** positive for AFB [and/or]**,** nucleic acid amplification test **that is** positive for [M.tb] ***Mycobacterium tuberculosis*****,** and/or a culture **that is** positive for [M.tb] ***Mycobacterium tuberculosis*** or [M.tb] ***Mycobacterium tuberculosis*** complex;

i. This applies only to specimens from sputum, [brochioalveolar] **bronchoalveolar** lavage, gastric aspirate, lung tissue**,** or other tissue of the respiratory tract such as the larynx or epiglottis;

2.-4. (No change.)

…

"TB Program" means the TB Program within the Division of HIV, STD, and TB Services of the Public Health Services Branch of the Department, for which the mailing address is TB Program, Division of HIV, STD, and TB Services, New

Jersey Department of Health, PO Box 369, Trenton, NJ 08625-0369, telephone (609) 826-4878, and telefacsimile (609) 826-4879.

…

8:57-5.4 Reporting requirements

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

(c) Health care providers and administrators may report the information required by the TB-70 form**, provided at Appendix N,** 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. (No change.)

2. Public health nurse case managers shall submit the TB-70 form**, provided at Appendix N,** to the TB Program [through the mailing address provided above].

(d) (No change.)

(e) The public health nurse case manager for an index case shall [mail any] **submit a** TB-41 form**, provided at** 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)-(h) (No change.)

(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,] **by telephone** whenever any patient with suspected or confirmed infectious or potentially infectious TB disease misses two consecutive appointments for medical assessment.

1.-2. (No change.)

(j) The administrator of a hospital shall report to the TB Program [at (609) 588-7522] **by telephone** 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] **by telephone** on the last business day that is at least 48 hours prior to the planned discharge date.

1.-2. (No change.)

(*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] **by telephone** 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. (No change.)

(m)-(o) (No change.)

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.-2. (No change.)

3. The patient is a resident of a congregate living facility, is [homeless] **unhoused,** or reports a private residence that the public health department has not verified as valid and stable, and had sputum smears **that were** initially positive for AFB.

i. (No change.)

[ii. The patient must have a nucleic acid amplification test negative for M. tuberculosis;]

Recodify existing iii.-iv. as **ii.-iii.** (No change in text.)

4. (No change.)

(b) (No change.)

8:57-5.6 Health officer responsibilities

(a) (No change.)

(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 for Tuberculosis Disease and Latent TB Infection."]

(c)-(e) (No change.)

8:57-5.8 Diagnostic evaluations

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

(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] **IGRA**, and a chest x-ray if the skin test is considered significant or the [interferon gamma release assay] **IGRA** is positive.

1. (No change.)

[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

(a) Health care providers may prescribe DOT as a method to monitor the adherence of a patient to [his or her] **the patient's** 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)-(e) (No change.)

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] **who** 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] **the patient's** 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] **the patient's** TB status to adequately protect the public health.

i.-ii. (No change.)

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] **the patient's** TB status to adequately protect the public health.

(b)-(*l*) (No change.)

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] **the patient's** place of work or school, or other premises where the health officer determines that such action is necessary to protect the public health.

1.-2. (No change.)

(b) (No change.)

(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. (No change.)

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] **the patient's** 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)-(j) (No change.)

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. (No change.)

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] **the patient's** risk for flight, the health officer shall immediately serve the patient an order of temporary commitment pursuant to this section, rather than an order for isolation due to the severity of the consequences of transmission.

(b)-(h) (No change.)

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] **the patient's** right to a hearing in the Superior Court.

1. (No change.)

(b)-(f) (No change.)

8:57-5.16 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] **https://www.nj.gov/health/hivstdtb/tb**, an annual report describing trends in prevalence and incidence of TB in New Jersey.

SUBCHAPTER 6. HIGHER EDUCATION IMMUNIZATION

REPEALS AND NEW RULES: 8:57-6.1 through 6.15

8:57-6.1 Scope

(a) This subchapter applies to every institution of higher education (IHE).

(b) Notwithstanding a religious exemption that might otherwise be available, this subchapter shall not be construed to limit a private entity's ability to exclude from enrollment or attendance at an IHE, a person, who does not have immunization or serologic immunity from:

1. A vaccine-preventable disease of which this subchapter requires evidence of immunization or serologic immunity; and/or

2. Another vaccine-preventable disease of which this subchapter does not require evidence of immunization or serologic immunity, provided the additional required immunization is consistent with ACIP recommendations, including applicable Catch-up Schedules, medical contraindications, and recognition of serologic immunity.

8:57-6.2 Designation of institutional liaison for IHEs

(a) The highest-ranking official within an IHE shall designate an institutional official, hereinafter referred to as the institutional liaison, and shall notify the Department of the designation using the Institutional Liaison Designation form at Appendix P.

(b) An institutional liaison shall:

1. Serve as the IHE's representative to the Department, specifically the VPDP, with respect to the Department's oversight of the IHE's compliance with this subchapter and other applicable laws governing immunization of collegians;

2. Have access to the immunization records that this subchapter requires the IHE to maintain; and

3. Administer and implement any corrective action that the Department requires the IHE to undertake to maintain the IHE's compliance with this subchapter.

(c) The highest-ranking official within an IHE shall notify the Department of changes to the identity or means to communicate with its designated institutional liaison by submitting a new Institutional Liaison Designation form provided at Appendix P to the Department within 30 days of a change.

8:57-6.3 IHE to require certain collegians to submit record of compliance with N.J.A.C. 8:57-4 pursuant to N.J.S.A. 18A:61D-1

(a) Pursuant to 18A:61D-1 et seq., and subject to N.J.A.C. 8:57-6.5 through 6.8, and 6.12, an IHE shall require every 1) full-time collegian who is 30 years of age or less and who enrolls or 2) part-time collegian in a program or course of study of the IHE leading to an academic degree, as a condition of the collegian's admission to and/or continued enrollment in the IHE, to submit to the IHE evidence of immunization pursuant to N.J.A.C. 8:57-6.4 for the diseases against which N.J.A.C. 8:57-4 requires immunization, according to the ACIP recommendations and any Catch-up Schedule then-applicable to the collegian.

(b) With respect to a collegian who provides, in whole or in part, insufficient evidence of immunization pursuant to subsection (a), above, an IHE shall require the collegian, as a condition of the collegian's admission to and/or continued enrollment in the IHE, to:

1. Obtain the vaccinations with respect to which the collegian is unable to satisfy subsection (a), above, in accordance with the ACIP recommendations then-applicable to the collegian, including an applicable Catch-up Schedule; and

2. Submit to the IHE documentation of compliance with subsection (a), above, in accordance with N.J.A.C. 8:57-6.4.

(c) An IHE shall not knowingly admit to or retain at the IHE any collegian who does not provide evidence of immunization in accordance with this section.

8:57-6.4 Evidence of immunization

(a) An IHE shall accept, and maintain as part of a collegian's immunization record pursuant to N.J.A.C. 8:57-6.13, the types of documentation listed in (b) below as evidence of a collegian's immunization, as administered by a healthcare professional, from those diseases against which N.J.A.C. 8:57-6.3, 6.10, and/or 6.11 require the collegian to present evidence of immunization if, alone or in combination with other items specified in (b) below, the documentation identifies:

1. The month, day, and year of administration of each required vaccine dose; or

2. Only the month and year of administration of each required vaccine dose if the totality of the documentation presented enables the IHE, in consultation

with the VPDP as may be necessary, to undertake the analysis and make the determination that subsection (c), below, requires.

(b) Subject to subsection (a), above, a record consistent with N.J.A.C. 8:57-4.4, above, is acceptable evidence of immunization.

(c) The IHE shall evaluate the evidence a collegian submits pursuant to this section, in consultation with the VPDP as necessary, to confirm that:

1. The collegian received those immunizations of which this subchapter requires the IHE to confirm that collegian's receipt;

2. The required doses were administered by a healthcare professional or a pharmacist; and

3. The dose of each vaccination was a valid dose.

(d) Subject to N.J.A.C. 8:57-6.5, an IHE shall require a collegian who is unable to present evidence that satisfies the IHE or the VPDP pursuant to paragraphs (c)1 and 2, above:

1. As applicable, to obtain missing doses and/or repeat invalid doses; and

2. Following a collegian's receipt of missing doses and/or repeat invalid doses, submit evidence of immunization within 10 days of receipt to the IHE as to these doses.

(e) An IHE shall make reasonable efforts to verify a document a collegian submits pursuant to this section if the IHE or the VPDP has reason to doubt the document's authenticity and/or content:

i. Upon the IHE's own initiative;

ii. In consultation with the Department, and/or

iii. Upon the request of the Department.

8:57-6.5 Evidence of immunity

(a) If a collegian is unable or unwilling to present evidence of immunization that complies with N.J.A.C. 8:57-6.4 or 6.10, an IHE shall admit and/or continue the enrollment of the collegian if the collegian presents evidence, compliant with (b) below, of laboratory serologic test results consistent with N.J.A.C. 8:57-4.5 of a collegian's immunity from or ongoing illness with diseases against which this subchapter requires the IHE to obtain evidence of immunization.

(b) An IHE shall make reasonable efforts to verify the authenticity and/or content of a document that a collegian submits pursuant to this section if the IHE or the VPDP has reason to doubt the document's authenticity and/or content:

1. Upon the IHE's own initiative;

2. Upon consultation with the Department, and/or

3. Upon the request of the Department.

8:57-6.6 Provisional admission and/or continued enrollment

(a) Subject to subsection (b), below, an IHE shall provisionally admit and/or continue the enrollment of a collegian who otherwise would be excludable pursuant to N.J.A.C. 8:57-6.3, as applicable, for the duration of one academic term, but no longer than four months, if the collegian:

1. Has received at least one valid dose of each immunization that N.J.A.C. 8:57-4, as applicable, requires, in accordance with the ACIP recommendations;

2. Is no later than 14 days behind in receiving the remaining doses in accordance with the applicable Catch-up Schedule (subject to an alternative schedule established in statute, such as that provided for the hep B vaccine); and

3. Receives the remaining doses in accordance with the applicable Catch-up Schedule and concurrently provides to the IHE evidence of immunization therewith consistent with N.J.A.C. 8:57-6.4, as applicable.

(b) An IHE shall admit to, and/or continue the enrollment in, the IHE a collegian, who otherwise would be excludable pursuant to N.J.A.C. 8:57-6.3, for the duration of the collegian's academic term, but no longer than four months, following admission and/or enrollment if the collegian is from outside of the USA and, within that period of admission and/or enrollment:

1. The collegian complies with N.J.A.C. 8:57-6.3, as applicable; or

2. The collegian:

i. Has received at least one valid dose of each required immunization that N.J.A.C. 8:57-6.3, as applicable, requires in accordance with the ACIP recommendations;

ii. Is no later than 14 days behind in receiving the remaining doses in accordance with the applicable Catch-up Schedule (subject to an alternative schedule established in statute, such as that provided for the hep B vaccine); and

iii. Receives the remaining doses in accordance with the applicable Catch-up Schedule of the ACIP recommendations and concurrently

provides to the IHE evidence of immunization therewith consistent with N.J.A.C. 8:57-6.4, as applicable.

8:57-6.7 Medical exemption from compliance with N.J.A.C. 8:57-6.3, 6.10, and/or 6.11 pursuant to N.J.S.A. 18A:61D-10 and 18A:62-15.2

(a) An IHE shall not require a collegian who is subject to N.J.A.C. 8:57-6.3, 6.4, 6.10, and/or 6.11 to comply therewith, with respect to an immunization that is medically contraindicated or presents a precaution for that collegian for a reason that the ACIP recommendations or the AAP Red Book specify as a vaccine contraindication.

(b) In support of an exemption pursuant to subsection (a), above, an IHE shall require a collegian to submit to the IHE a Request for Medical Exemption from Mandatory Immunization at Appendix L or another document consistent with N.J.A.C. 8:57-4.7(b).

(c) The IHE shall:

1. Review a statement submitted pursuant to this section for compliance with subsections (a) and (b), above;

2. Retain the statement as part of the collegian's immunization record pursuant to N.J.A.C. 8:57-6.13;

3. Review the grant of an exemption at least annually or by the end of the period of contraindication specified in paragraph (b)2, above, whichever is earlier; and

4. If applicable, as a condition of the collegian's admission to and/or continued enrollment in the IHE, ensure that the collegian complies with N.J.A.C. 8:57-6.3, 6.10, and 6.11, as applicable, upon the conclusion of the period of contraindication that is specified in the statement submitted pursuant to paragraph (b)2, above.

(d) An IHE can consult with the VPDP to obtain assistance in reviewing a statement for compliance with this section and determining whether the reason specified as a contraindication or precaution pursuant to paragraph (b)3, above, is a reason that the ACIP recommendations or the AAP Red Book identify or recognize as a vaccine contraindication or precaution.

8:57-6.8 Religious exemption from compliance with N.J.A.C. 8:57-6.3 pursuant to N.J.S.A. 18A:61D-3 and 26:1A-9.1

(a) An IHE shall not require a collegian to submit a record of compliance in accordance with N.J.A.C. 8:57-6.3 if the collegian, or the collegian's parent if the collegian is a minor, submits a written, signed statement to the IHE that requests an exemption from a specific required immunization and indicates that:

1. The specific required immunization "conflicts with" the collegian's "religious beliefs" (see N.J.S.A. 18A:61D-3); or

2. The specific required immunization "interferes with the free exercise of the" collegian's "religious rights" (see N.J.S.A. 26:1A-9.1).

(b) The IHE shall require a collegian to comply with N.J.A.C. 8:57-6.3 with respect to immunizations as to which the collegian does not assert a religious conflict or interference pursuant to paragraphs (a)1 or 2, above.

(c) An IHE shall not grant an exemption pursuant to subsection (a), above, on the sole basis of a collegian's general moral or philosophical objection to immunization.

(d) An IHE shall retain a statement that a collegian submits pursuant to subsection (a), above, in the collegian's immunization record pursuant to N.J.A.C. 8:57-6.13.

(e) Subject to subsections (f) and (g), below, an IHE shall not require a collegian who obtains an exemption pursuant to this section to reapply annually for the exemption.

(f) If a collegian obtains an exemption pursuant to this section and thereafter consents to and does receive a vaccination that N.J.A.C. 8:57-6.3 requires, in contravention of the statement the collegian submitted pursuant to subsection (a), above, the IHE shall treat the exemption as inapplicable to further immunizations that, but for the exemption, N.J.A.C. 8:57-6.3 would require the collegian to receive.

(g) A collegian whose religious exemption on file with an IHE becomes inapplicable pursuant to subsection (f), above, must reapply for a religious exemption pursuant to this section if the collegian wants to assert an exemption from any subsequent doses of immunizations that N.J.A.C. 8:57-6.3 would require the collegian to receive.

8:57-6.9 Exclusion of collegian due to vaccine-preventable diseases pursuant to N.J.S.A. 18A:62-15.2 and 26:1A-9.1, and 26:4-6

(a) Notwithstanding N.J.A.C. 8:57-6.6, 6.7, 6.8, and 6.12, if the Commissioner determines that a suspected or confirmed vaccine-preventable disease outbreak exists, an IHE shall exclude, in accordance with direction of the local health agency with jurisdiction or the Department, unimmunized, under-immunized, and provisionally admitted collegians from attendance at the IHE during the suspected or confirmed vaccine-preventable disease outbreak.

(b) Pursuant to N.J.S.A. 26:4-6, "Any body having control of a school may, on account of the prevalence of any communicable disease, or to prevent the spread of communicable diseases, prohibit the attendance of any teacher or pupil of any school under their control and specify the time during which the teacher or scholar shall remain away from school."

(c) To implement subsections (a) or (b), above, the local health agency with jurisdiction or the Department shall determine, and provide corresponding direction to the IHE about:

1. The "prevalence" of a communicable disease;

2. The necessity of the prohibition from attendance of a person to prevent the spread of the communicable disease;

3. The categories of persons, based on immunization status, that the IHE is to prohibit from attendance; and

4. The time during which the prohibition from attendance is to remain in effect.

(d) An IHE, through its institutional liaison, shall maintain a record of collegians admitted to the IHE pursuant to N.J.A.C. 6.6, 6.7, 6.8, and 6.12, and make an up-to-date list of those collegians available to the Department and/or the local health agency with jurisdiction, upon request.

8:57-6.10 IHEs to require certain collegians to submit record of compliance with N.J.S.A. 18A:61D-9 regarding immunization against or immunity to hepatitis B

(a) Pursuant to N.J.S.A. 18A:61D-9, and subject to N.J.A.C. 8:57-6.7, 6.8, and 6.12, and (c) below, as a condition of a collegian's admission to or continued enrollment in an IHE, an IHE shall require every collegian, regardless of age, to comply with (b) below if the collegian:

1. Registers for 12 or more credit hours of course study per semester or term; and

2. Enrolls in a program of the IHE leading to an academic degree.

(b) A collegian who is subject to subsection (a), above, shall submit evidence compliant with:

1. N.J.A.C. 8:57-6.4, showing that the collegian has completed the hepatitis B immunization series that is applicable to that collegian as specified in the ACIP recommendations within nine months of the date the collegian first commences to attend the IHE; or

2. N.J.A.C. 8:57-6.5, showing that the collegian has immunity from or ongoing illness with hepatitis B consistent with N.J.A.C. 8:57-4.5(a)2.

(c) This section shall not extend the time within which an IHE is to obtain evidence of hepatitis B immunization or immunity from a collegian who is subject to N.J.A.C. 8:57-6.3.

(d) An IHE that obtains evidence of hepatitis B immunization or immunity from a collegian pursuant to N.J.A.C. 8:57-6.4 and 6.5 is deemed compliant with this section and shall not require that collegian to resubmit evidence of hepatitis B immunization or immunity pursuant to this section.

(e) An IHE shall not knowingly admit to, or retain at, the IHE a collegian who does not provide evidence of hepatitis B immunization or immunity compliant with this section.

(f) An IHE shall not grant provisional admission pursuant to N.J.A.C. 8:57-6.6 to a collegian described in subsection (a), above, with respect to submission of the evidence of immunization or immunity that this section requires.

8:57-6.11 IHEs to require collegian to submit record of compliance with N.J.S.A. 18A:62-15.1 regarding meningococcal-containing vaccination

(a) Pursuant to N.J.S.A. 18A:62-15.1, and subject to N.J.A.C. 8:57-6.8 and 6.12, as applicable, an IHE shall require a collegian specified in (b) below, as a condition of the collegian's enrollment in the IHE, to submit to the IHE evidence compliant with N.J.A.C. 8:57-6.4 that the collegian has received meningococcal-containing

vaccination in accordance with ACIP recommendations then-applicable to the collegian.

(b) Subsection (a), above, applies to all collegians, regardless of age, who enroll in an IHE.

(c) An IHE shall not knowingly admit to or retain at the IHE any collegian who does not comply with this section.

8:57-6.12 Religious exemption from compliance with N.J.A.C. 8:57-6.10 and 6.11 pursuant to N.J.S.A. 18A:61D-10 and 18A:62-15.2

(a) An IHE shall not require a collegian who is subject to N.J.A.C. 8:57-6.10 and/or 6.11 to comply therewith if the collegian, or the collegian's parent if the collegian is a minor, submits a written, hand-signed statement to the IHE requesting an exemption from compliance with either section that explains "how the administration of the vaccine conflicts with the bona fide religious tenets or practices of the" collegian and/or the collegian's parent, if the collegian is a minor (see N.J.S.A. 18A:61D-10 and 18A:62-15.2).

(b) An IHE shall not grant an exemption from a collegian's compliance with N.J.A.C. 8:57-6.10 and/or 6.11 on the sole basis of a general philosophical or moral objection to immunization on the part of the collegian and/or, if the collegian is a minor, the collegian's parent.

(c) A religious-affiliated IHE has the authority to withhold or grant a request for exemption made pursuant to this section without challenge by any secular health authority.

(d) An IHE shall retain a statement that a collegian submits pursuant to subsection (a), above, in the collegian's immunization record in accordance with N.J.A.C. 8:57-6.13.

(e) An IHE shall not require a collegian who obtains an exemption pursuant to this section to reapply annually for the exemption.

8:57-6.13 IHE's obligations with respect to collegians' immunization records pursuant to N.J.S.A. 18A:61D-1

(a) With respect to records that this subchapter requires an IHE to collect, establish, and/or maintain, the IHE, through its institutional liaison, shall:

1. Maintain the records in a manner that renders them accessible to public health officials without compromising the confidentiality of collegians' other educational or medical records;

2. Make the records available to authorized representatives of the Department and the local health agency with jurisdiction:

i. For routine inspection upon 24 hours' notice; and

ii. For immediate inspection during confirmed or suspected vaccine-preventable disease outbreaks or other public health emergencies; and

3. Ensure that each record is compliant with respect to the required content and origin of documentation of the following, as applicable:

i. Evidence of immunization pursuant to N.J.A.C. 8:57-6.4;

ii. Evidence of immunity pursuant to N.J.A.C. 8:57-6.5;

iii. Medical exemption pursuant to N.J.A.C. 8:57-6.7; and

iv. Religious exemptions pursuant to N.J.A.C. 8:57-6.8 and/or 6.12.

(b) Upon request of a collegian, and in accordance with policies and procedures that an IHE establishes with respect to its handling of collegians' requests for their educational, and other medical, records and transcripts, an IHE shall:

1. Issue a copy, an electronic print-out, or a duplicate in another medium, of a collegian's immunization record, including supporting statements, such as medical or religious exemption documentation (hereinafter collectively referred to as an "immunization transcript");

2. Authenticate the immunization transcript in the same manner as that in which it would authenticate a collegian's educational transcript; and

3. Transmit the immunization transcript to the collegian or, at the direction of the collegian, to another IHE within or outside the State.

(c) An IHE shall retain a collegian's immunization transcript, and address a collegian's request for copies or transmittal thereof pursuant to subsection (b), above, consistent with the policies and procedures that the IHE establishes with respect to the retention method and period the IHE applies to, and the process by which the IHE addresses a collegian's request for copies and/or transmittal of, a collegian's educational, and other medical records and transcript.

8:57-6.14 IHEs to offer hepatitis B and meningococcal-containing vaccine pursuant to N.J.S.A. 18:61D-9 and 18A:62-15.1

(a) An IHE shall make the following vaccinations available to collegians through the IHE's student health services program or through a contractual agreement with a community-based health service in proximity to the IHE:

1. Hepatitis B; and

2. Meningococcal-containing vaccine.

8:57-6.15 Certain IHEs to offer information about meningitis and meningococcal-containing vaccine immunization requirement pursuant to N.J.S.A. 18A:61D-7

(a) Each IHE shall:

1. Provide to all prospective collegians, regardless of age, prior to their matriculation, the Department brochure entitled "Meningococcal Disease: Are You Protected," available within the Implementation of Meningococcal Vaccine Requirements guidance at https://www.nj.gov/health/cd/documents/topics/meningo/are_you_protected.pdf; and

2. Develop procedures:

i. To obtain and record each prospective collegian's response to the information the IHE provides pursuant to paragraph (a)1, above;

ii. To assess prospective collegians' compliance with N.J.S.A. 18A:62-15.1 and N.J.A.C. 8:57-6.11; and

iii. To memorialize whether prospective students who are exempt from compliance with N.J.S.A. 18A:62-15.1 and N.J.A.C. 8:57-6.4 and/or 6.11 nonetheless decide to receive the meningococcal-containing vaccine following receipt of the information the IHE provides pursuant to paragraph (a)1, above.

REPEAL N.J.A.C. 8:57-6.16

8:57-[6.17]**6.16** Reports to be submitted to the Department

Each [institution] **IHE, through its institutional liaison,** shall [provide a report of the immunization status of students] **report the immunization status of the collegians attending or enrolled in the IHE for each campus location by December 1 of** each year [to] **by submission of** the [Department using] **information required in** the Annual College Immunization Status Report (IMM-3), available in [the subchapter] Appendix **Q:**

1. Electronically; or

2. In the NJIIS.

[1. The official designated pursuant to N.J.A.C. 8:57-6.11(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 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.

(c) The 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.

(d) Each four-year institution of higher education shall complete the meningococcal section of the Annual College Immunization Status by December 1, for each academic year which begins in September of the same year.

(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.]

REPEAL: N.J.A.C. 8:57-6.18 through 6.21