

HEALTH AND SENIOR SERVICES
PUBLIC HEALTH SERVICES BRANCH
DIVISION OF EPIDEMIOLOGY, ENVIRONMENTAL AND
OCCUPATIONAL HEALTH
COMMUNICABLE DISEASE SERVICE
VACCINE PREVENTABLE DISEASE PROGRAM

Communicable Diseases

New Jersey Immunization Information System

Proposed New Rules: N.J.A.C. 8:57-3

Authorized By: _____ Heather Howard,

Commissioner, Department of Health and Senior Services in
consultation with the Public Health Council, Herbert Yardley, M.A.,
Chair.

Authority: N.J.S.A. 26:4-131 et seq., particularly 26:4-134(i).

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

Proposal Number: PRN 2008 - .

A public hearing on the proposed new rules will be held between
10:00 A.M. and 11:00 A.M., or until completion of testimony from persons
on the list of speakers, whichever is later, on _____, 2008
at the following location:

New Jersey Department of Health and Senior Services

First Floor Auditorium
Health and Agriculture Building
369 South Warren Street (at Market Street)
Trenton, NJ 08608

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

Persons wishing to comment on the notice of proposal at the public hearing are requested to telephone Ms. Chari Otero at (609) 588-7512 by _____, 2008 to be placed on the list of speakers and to bring an extra written copy of their remarks for submission to the public record. Speakers will be limited to three minutes. The Hearing Officer will give persons who do not pre-register to speak an opportunity to speak if time permits.

The agency proposal follows:

Summary

Former Governor McGreevy approved the Statewide Immunization Registry Act (Act), P.L. 2004, c.138 codified at N.J.S.A. 26:4-131 et seq., on September 2, 2004. N.J.S.A. 26:4-134(a) designates the New Jersey Immunization Information System (NJIS) as the Statewide automated and electronic immunization registry and the single repository of immunization records in the State. N.J.S.A. 26:4-134(i) directs the Commissioner of the

Department of Health and Senior Services (Department), in consultation with the Public Health Council, to adopt rules to effectuate the purposes of the Act. The Department proposes new rules at N.J.A.C. 8:57-3 to fulfill this statutory mandate. On April 21, 2008, the Department proposed to readopt N.J.A.C. 8:57 with amendments, new rules, and repeals at 40 N.J.R. 1962(a). As part of that rulemaking, the Department proposed to recodify existing N.J.A.C. 8:57-3, covering Occupational and Environmental Diseases, Injuries, and Poisonings into its own chapter at N.J.A.C. 8:58. Upon the Department's adoption of the April 21, 2008 notice of proposal, N.J.A.C. 8:57-3 will be a reserved subchapter and available for the NJIIS rules, proposed as new rules in this rulemaking.

The Department's proposed new rules at N.J.A.C. 8:57-3 would implement N.J.S.A. 26:4-131 et seq. and establish the administration and procedures involved in the operation of the NJIIS. The Department has operated the NJIIS on a Statewide basis since 1997 and developed its web-enabled capacity in 2002. There are approximately 1,200 private medical offices, 293 public clinics, and 400 schools that the Department has authorized to have access to the NJIIS. The 61 birthing hospitals enroll approximately 93,000 newborns into the NJIIS each year. The proposed new rules would set forth the NJIIS operational standards and procedures and would apply to all registrants and authorized users. The proposed new rules would set forth the standards for the establishment

and maintenance of the NJIIS, including, but not limited to, definitions of terms, authorized user enrollment and training, submitting and retrieving information, mandatory reporting of administered vaccine doses, contents of submissions, procedures for birthing facilities and health care providers, as appropriate, informing parents about the NJIIS, registrant enrollment and withdrawal, amending information, limiting access, maintaining confidentiality, generating reports, penalties, immunities, enforcement, appeals, and required forms.

A summary of the proposed new rules follows:

Proposed new N.J.A.C. 8:57-3.1 would establish the purpose and scope of the rules and the purpose of the NJIIS.

Proposed new N.J.A.C. 8:57-3.2 would provide a list of all the documents that the Department is proposing to incorporate by reference in the subchapter. The Department proposes to incorporate by reference, as amended and supplemented, the following documents in Subchapter:

1. The 2001 Immunization Registry Minimum Functional Standards, which contain recommendations made by the National Immunization Program's Technical Working Group on the minimum technical functions of immunization registries;
2. The Implementation Guide for Immunization Data Transactions using Version 2.3.1 of the Health Level Seven (HL7) Standard Protocol (June 2006), which describes the most frequently used segments of registries in their entirety and the HL7 specifications for

electronic data interchange; 3. Recommended Immunization Schedules for Persons Aged 0 – 18 Years – United States, 2008, which contain the immunization recommendations of the Advisory Committee on Immunization Practices (ACIP) of the Centers for Disease Control and Prevention (CDC) of the U.S. Department of Health and Human Services as approved by the American Academy of Pediatrics (AAP) and the American Academy of Family Physicians (AAFP); 4. The Recommendations for Preventive Pediatric Health Care (RE9535) which sets forth the schedule for pediatric health care providers to perform certain medical screenings and procedures, including immunizations, and other preventive health activities based on the age of a child; and 5. The Immunization Registry Certification: Recommendation of the National Immunization Program’s Technical Working Group (TWG) (June 4, 2002), which establishes the minimum registry functional standards for voluntary certification. The Department proposes to incorporate by reference the following forms in this subchapter: 1. Enrollment Request for New NJIIS Site, available at Appendix A; 2. User Enrollment and Training Request available at Appendix B; 3. User Confidentiality Agreement, available at Appendix C; 4. Request for Change of User Security Authorization/Request for Password Reset, available at Appendix D; 5. NJIIS Informational Brochure, available at Appendix E; 6. Consent to Participate, available at Appendix F; 7. Declination of Newborn Automatic

Enrollment, available at Appendix G; 8. Request For Change to NJIIS Immunization Record, available at Appendix H; 9. Request for Copy of NJIIS Immunization Record, available at Appendix I; and 10. Registrant Withdrawal from NJIIS, available at Appendix J. Proposed new N.J.A.C. 8:57-3.2 would also set forth the methods by which the public may obtain each document above and that the proposed forms would be available at the webpages set forth in this proposed section upon publication of the notice of adoption of N.J.A.C. 8:57-3 in the New Jersey Register.

Proposed new N.J.A.C. 8:57-3.3 would set forth the definitions of the following words and terms utilized in this subchapter: “Administrator,” “authorized user,” “billing vendor,” “biological,” “birth center,” “birthing facility,” “collaborating public health programs,” “college,” “designated agent,” “electronic birth certificate or EBC,” “health care provider,” “health benefits plan,” “health employer data information set or HEDIS,” “local health agency,” “Local information Network and Communications System or LINCS,” “Maternal and Child Health Consortia or MCHC,” “minor,” “newborn,” “NJ FamilyCare Program,” “NJ Medicaid Program,” “NJIIS,” “NJIIS immunization record,” “NJIIS site,” “NJIIS webpage,” “parent,” “practice management vendor,” “primary health care provider,” “registrant,” “responsible person,” “site administrator,” “tracking and reminder or recall module,” “university,” “vaccine,” “Vaccines for Children Program or VFC,” “VPDP,” and “VPDP mailing address.”

Proposed new N.J.A.C. 8:57-3.4 would establish the confidentiality principles, which govern the operation of the NJIIS as to the protections afforded an individual registrant's personal information. Proposed new N.J.A.C. 8:57-3.4 would set forth limits on the sharing of information contained within the NJIIS with health benefits plans, local health officers, out-of State recognized immunization registries, investigatory or enforcement authorities, providers furnishing services, and health care payors.

Proposed new N.J.A.C. 8:57-3.5 would articulate the responsibility of the Department's Vaccine Preventable Disease Program (VPDP) for administration of the NJIIS. Proposed new N.J.A.C. 8:57-3.5 would articulate the delegation of certain NJIIS administrative functions, including enrollment, training, and quality assurance, from the Department to the local Maternal Child Health Consortia (MCHC). Proposed new N.J.A.C. 8:57-3.5 would set forth the methods by which the VPDP would provide notice of the VPDP's designation of another organization to assume the responsibilities of the MCHC.

Proposed new N.J.A.C. 8:57-3.6 would establish the list of persons and entities that are eligible to become authorized users and thereafter, access the NJIIS. Proposed new N.J.A.C. 8:57-3.6 would articulate the Commissioner's authority to expand the list.

Proposed new N.J.A.C. 8:57-3.7 would establish three prerequisite conditions, which an applicant must satisfy in order to enroll as an authorized user. The proposed prerequisites are agreeing to use NJIIS to promote public health, completion of a User Confidentiality Agreement, and completion of NJIIS training.

Proposed new N.J.A.C. 8:57-3.8 would establish the process for applying to become a NJIIS authorized user through the MCHC, applicable to prospective eligible entities and designated agents.

Proposed new N.J.A.C. 8:57-3.8 would set forth the required enrollment forms and documents and the available levels of access for designated agents. Proposed new N.J.A.C. 8:57-3.8 would set forth the standards by which MCHCs will determine whether or not to enroll prospective eligible entities and designated agents. Proposed new N.J.A.C. 8:57-3.8 would set forth the training requirements for authorized users, assignment of a user identification and temporary password, and the process for changing a password or access level.

Proposed new N.J.A.C. 8:57-3.9 would establish the access rights and limitations that each authorized user would have to the NJIIS.

Proposed new N.J.A.C. 8:57-3.10 would establish the procedure for a site administrator to withdraw or change an authorized user's access to the NJIIS.

Proposed new N.J.A.C. 8:57-3.11 would establish procedures for birthing facilities and health care providers to inform parents about the NJIIS through provision of the NJIIS Informational Brochure and document such provision in the permanent medical record of the newborn or minor. Proposed new N.J.A.C. 8:57-3.11 would articulate when birthing facilities and/or health care providers must provide the Declination of Newborn Automatic Enrollment form or Consent to Participate form to parents and requirements for retaining copies, respectively.

Proposed new N.J.A.C. 8:57-3.12 would establish the process for registrant enrollment. Proposed new N.J.A.C. 8:57-3.12 would articulate that birthing facilities will automatically enroll all newborns born on or after January 1, 1998, unless the parent has completed a Declination of Newborn Automatic Enrollment form. Proposed new N.J.A.C. 8:57-3.12 would set forth recordkeeping requirements for birthing facilities regarding administration of vaccine or biological to an enrolled newborn. Proposed new N.J.A.C. 8:57-3.12 would also establish the process for registrant enrollment for those minors not enrolled by a birthing facility or born prior to January 1, 1998, or for adult registrants.

Proposed new N.J.A.C. 8:57-3.13 would establish the process by which a registrant, or parent of a registrant if the registrant is a minor, can obtain a printout of the registrant's NJIIS immunization record and set forth

recordkeeping requirements for health care providers that fulfill such requests.

Proposed new N.J.A.C. 8:57-3.14 would establish the process by which a parent of a minor registrant, or registrant may request an amendment to the demographic or medical information contained in NJIS. Proposed new N.J.A.C. 8:57-3.14 would set forth the appropriate form to make such request, and that a health care provider must process such request in compliance with the Health Insurance Portability and Accountability Act (HIPAA) of 1996, 42U.S.C. §1301 et seq. and the rules promulgated thereunder, and the criteria by which an authorized user may deny such request. Proposed new N.J.A.C. 8:57-3.14 would set forth the time frame in which an authorized user must address the documentation of the request and response, retention of all documents related to the amendment of record process, and the review of all denials by the VPDP.

Proposed new N.J.A.C 8:57-3.15 would establish the process by which a registrant, or parent of a minor registrant, may withdraw the registrant from the NJIS at any time.

Proposed new N.J.A.C. 8:57-3.16 would establish that as of January 1, 2011 all health care providers that immunize children less than seven years of age would be required to enroll as NJIS authorized users, commence online reporting, and report the administration of vaccines to children less than seven years of age within 30 days of vaccine

administration. Proposed new N.J.A.C. 8:57-3.16 would set forth the methods by which health care providers may report vaccinations to the NJIIS. Proposed new N.J.A.C. 8:57-3.16 would list the demographic and vaccine administration data necessary to build and maintain an accurate and complete immunization record. Proposed new N.J.A.C. 8:57-3.16 would permit health care providers to report vaccines they administered to persons seven years of age or older that are registrants, previously administered but not reported vaccine doses, or vaccines administered by another health care provider, provided there is adequate documentation, however such reporting is not mandatory. Proposed new N.J.A.C. 8:57-3.16 would prohibit authorized users from reporting vaccines administered to those registrants who have either declined to participate in, or withdrawn from, the NJIIS. Proposed new N.J.A.C. 8:57-3.16 would allow non-participating NJIIS health care providers to notify the VPDP of any potential errors in a registrants NJIIS record.

Proposed new N.J.A.C. 8:57-3.17 would establish that an authorized user may elect to utilize the NJIIS tracking/reminder recall function to notify by mail, telephone, or through personal contact, as applicable, a registrant or a minor registrant's parent that a vaccination is coming due or is overdue according to the national Recommended Immunization Schedules for Persons Aged 0 – 18 Years and the Recommendations for Preventive Pediatric Health Care (RE9535).

Proposed new N.J.A.C. 8:57-3.17 would establish that a registrant or minor registrant's parent may decline participation of the registrant in the optional immunization tracking application, while remaining an active registrant in NJIIS.

Proposed new N.J.A.C. 8:57-3.18 would establish that a registrant's immunization history as portrayed in a NJIIS immunization record is an adequate documentation format for the purpose of determining a registrant's admission to a licensed child care center, school, college, or university, as they assess pupil compliance with the existing State immunization requirements established at N.J.A.C. 8:57-4 and 6.

Proposed new N.J.A.C. 8:57-3.19 would establish that the reporting and submission of vaccinations and other preventative health screening information to the NJIIS shall only occur through an electronic and secure format as provided by the Department and described in this section.

Proposed new N.J.A.C. 8:57-3.19 would establish that the Department is permitted to transmit, share, or exchange immunization data contained within the NJIIS with other recognized and established state or regional immunization registries having confidentiality and security protections consistent with the NJIIS. Proposed new N.J.A.C. 8:57-3.19 establishes that the Department's data exchange policies will be consistent with the Implementation Guide for Immunization Data Transactions.

Proposed new N.J.A.C. 8:57-3.20 would articulate the Department's policy on releasing reports generated from the NJIIS and would establish that reports of registrants that include individual level data are not government records subject to public access or inspection within the meaning of N.J.S.A. 47:1A-1 et seq. Proposed new N.J.A.C. 8:57-3.20 would prohibit individuals and entities from using information contained in, or reports generated from, the NJIIS in a punitive manner against any authorized user or for a profit motive, pecuniary or marketing purpose.

Proposed new N.J.A.C. 8:57-3.21 would establish immunity from liability for divulging confidential registrant information for any authorized user submitting vaccine information to the NJIIS in good faith for public health purposes. Proposed new N.J.A.C. 8:57-3.21 would establish immunity from liability for any error or inaccuracy contained in NJIIS information for any authorized user that reports, retrieves, or discloses information relating to the NJIIS.

Proposed new N.J.A.C. 8:57-3.22 would articulate the penalties that the Department may assess as a result of knowingly entering false or improper data, health care provider's failure to complete the mandatory enrollment and reporting, or a provider's failure to timely report and submit required information to the NJIIS.

Proposed new N.J.A.C. 8:57-3.23 would establish the appeal process for an applicant denied participation in NJIIS or an authorized user whose access to the NJIIS has been suspended or revoked.

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

Social Impact

The proposed new subchapter has the potential to provide an immediate and future social impact upon over 109,000 newborns and their families each year, 4,000 child care centers, 3,665 schools, and 47 colleges and universities who choose to participate in the NJIIS. There are 61 hospitals with birthing facilities and 4,000 private physicians who would be required to participate in the NJIIS. Approximately 93,000 or 85 percent of newborns each year are enrolled in the NJIIS through the electronic birth certificate process which establishes the initial NJIIS record containing the child's demographic information on the NJIIS database. By December 2007, there were 1,228,428 persons registered in and 11,535,763 doses of vaccines documented as administered in the database. However, many records are incomplete since non-participation in the NJIIS by many private health care providers due to its voluntary nature since 1997, has limited the functional utility of the NJIIS as a

population-based resource for those whom might realize greater benefit from access and increased utilization.

The proposed subchapter would have a positive social impact since the NJIIS would be formally recognized as the official Statewide Immunization Registry and would foster greater health care provider and parental participation in the immunization process, while maintaining confidentiality as set forth in the proposed rules. Despite significant progress related to increased vaccine coverage levels over the past decade, and the consequent decreased incidence of vaccine-preventable diseases, there still remains a risk to those unimmunized or incompletely immunized children in New Jersey. Approximately 24 percent of two-year old New Jersey children still lack the recommended vaccines. The fully operational NJIIS would help parents and their health care providers who directly perform preventive health services, such as immunization, to assure timely childhood immunizations while providing a permanent electronic immunization and preventive health screening record. Recommended vaccinations and preventive health screenings are often deferred or unnecessarily repeated when an immunization or preventive health screening record is either unknown or not available. An immunization registry creates a permanent, reliable, and accurate record, which is readily available and is beneficial when a registrant or family moves or changes health care providers.

Access to the NJIIS by schools, child care centers, colleges, and universities, for those who choose to participate, would promote a more efficient review of immunization documents and reduce follow-up work required of parents, health care provider staff, and school staff necessary to confirm compliance with the various educational facilities, which require immunization information for pupil enrollment and continued attendance.

Access to the NJIIS by health benefits plans would provide them with a more complete database of their covered patients' immunization records allowing a more efficient method to maintain and access a child's immunization history. Access to the NJIIS by health benefits plans would also promote more efficient reporting on their organizational efforts to appropriately vaccinate all their covered minors with the recommended vaccines at the appropriate time to the Health Employer Data Information Set (HEDIS), which is a quality of care measurement tool created by the National Committee for Quality Assurance.

Access to the NJIIS for Department and local health agency officials also offers the possibility to identify specific geographic areas demonstrating lower immunization levels, suggesting the need for increased focus or public health intervention activities to improve vaccine coverage rates. A fully utilized and populated registry would be congruent with ongoing national and commercial information technology initiatives such as the development of electronic medical patient health records,

health data integration, and health database interfaces to improve the quality and efficiency of health care services.

NJIS participation, utilization, and access would serve to promote the public health objective of decreasing the prevalence of childhood vaccine-preventable disease through increased vaccine coverage levels, while providing direct social benefits for parents, registrants, health care providers, local health agencies and the Department, schools, and health benefits plans. The Department anticipates a positive reaction to the proposed subchapter from parents and New Jersey's health care community.

Economic Impact

The proposed rules may impose some economic impact upon approximately 4,000 medical practitioners and other public health clinics that vaccinate children less than seven years of age or alternatively their contracted billing or practice management vendors, or registrants' insurers collecting vaccination administration data. There are also approximately 61 hospitals providing birth services, which would be required to report the first dose of hepatitis-B vaccine being administered to newborns. Those physicians or clinics without computer equipment in their office may need to purchase hardware to access the NJIS database in order to determine the registrant's past immunization and preventive health screening history and to subsequently report the doses of vaccines they administer to the

registrant. There may be incremental attendant labor costs of computer data entry, if information related to immunization administration is not already being captured electronically in the medical office or on another database in an electronic format that can interface with the NJIIS. The possible costs related to computer hardware purchases, internet access fees, software overlays, and data entry labor costs can be planned for, and incrementally addressed, since the proposed reporting requirement would not become operative until January 1, 2011. The proposed new rules do not require retention of professional services although, authorized users may choose to retain those services with regard to technological needs. There is no user fee to enroll as an authorized user or to access the NJIIS.

The widespread use of a fully functional population-based immunization registry over time would result in cost savings realized by the following anticipated outcomes: the timely and safer provision of immunization services by providers, both private and public; more complete health insurance carrier and benefits plan HEDIS reporting; an easier process for child care centers, schools, universities and colleges to assure pupil compliance with State immunization requirements; reduction of staff time in researching immunization histories; more accurate and less labor intensive assessments of vaccine coverage levels for quality improvement purposes; and more complete and accurate immunization

coverage assessments for a specific geographic region or locale to demonstrate effectiveness of ongoing projects or to suggest special health initiatives or interventions to improve the public health. Therefore, utilization of the NJIIS would affect cost savings for parents, private practitioners, hospitals, public clinics, health benefits plans, educational institutions, and local health agencies alike.

Federal Standards Statement

The proposed new rules are mandated by N.J.S.A. 26:4-131 et seq., particularly N.J.S.A. 26:4-134(i), and are not subject to any Federal standards or requirements. As discussed more thoroughly in the Summary above, the Department has elected to incorporate by reference in the proposed new rules the following Federal documents: 2001 Immunization Registry Minimum Functional Standards, Implementation Guide for Immunization Data Transactions using Version 2.3.1 of the Health Level Seven (HL7) Standard Protocol (June 2006), 2008 Childhood and Adolescent Immunization Schedule, Recommendations for Preventive Pediatric Health Care (RE9535), and Immunization Registry Certification: Recommendation of the National Immunization Program's Technical Working Group (TWG) (June 4, 2002). At proposed new N.J.A.C. 8:57-3.14 the Department requires health care providers to respond to a registrant's request for change to medical information in a NJIIS record in

compliance with the Health Insurance Portability and Accountability Act (HIPAA) of 1996, 42U.S.C. §1301 et seq. and the rules promulgated thereunder, to the extent that health care providers are already required to comply with HIPAA. The Department does not exceed any Federal standards and therefore, a Federal standards analysis is not required.

Jobs Impact

The Department does not anticipate that the proposed new rules would result in the generation or loss of jobs in New Jersey. However, health care providers may decide to hire additional staff to complete the proposed reporting and recordkeeping requirements.

Agriculture Industry Impact

The proposed new rules would not have an impact on the agriculture industry in New Jersey.

Regulatory Flexibility Analysis

The proposed new rules would have an impact on small businesses as they are defined in the Regulatory Flexibility Act, N.J.S.A. 52:14B-16 et seq., since child care centers, some non-public schools, local health agencies, health care providers, and health benefits plans may have less than 100 full time employees. The proposed NJIIS compliance, reporting, and recordkeeping requirements, as described in the Summary above, would most likely affect the approximately 4,000 physicians in New Jersey who routinely provide primary pediatric care. Some infrastructure

and operational costs may accrue among some of the various entities listed above related to the purchase of computer hardware equipment, software training, software overlay, internet access, and possible data entry as described in the Economic Impact above.

The Department has sought to reduce some user costs associated with manual data entry for health care providers, hospitals, and clinics by establishing electronic interfaces with the NJ Medicaid Program, NJ FamilyCare Program and the New Jersey Electronic Birth Certificate System, to provide an easier means to submit data to the NJIIS. The Department has also developed and implemented similar interfaces with the Department's collaborating public health programs, the New Jersey Vaccines for Children Program, health benefits plans, and other preventive health screening programs that may maintain NJIIS relevant information. The use of electronic interfaces reduces the burden of manually entering the same immunization data into multiple databases. The Department has also limited the scope and burden of the mandatory reporting requirements for health care providers to report information on only those registrants less than seven years of age and has provided an approximate two-year preparation and implementation period. The Department cannot provide exemptions from these proposed rules or lesser requirements to small businesses, due to the need to meet the purpose of the NJIIS to provide as complete a population-based system

as possible in order effect overall improvement in the rate of vaccine preventable diseases and other adverse medical conditions.

The proposed reporting and recordkeeping requirements, as outlined in the Summary above, are necessary to maximize participation in the NJIIS, and generate utility for the medical community. The Department has developed the proposed new rules to improve the efficiency of delivering and documenting vaccine administration and preventive health screenings for the benefit of registrants, parents of registrants, health care providers, schools, health benefits plans, local health agencies, State public health programs, and private organizations that are authorized users of the NJIIS.

Smart Growth Impact

The proposed new rules would not have an impact on the achievement of smart growth and the implementation of the State Development and Redevelopment Plan.

Full text of the proposed new rules follows:

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 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 (NJIS) as the official Statewide immunization registry 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 NJIS.

(b) The purpose of the NJIS 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) This subchapter applies to all authorized users and registrants.

8:57-3.2 Incorporated documents

(a) To further the purposes of N.J.S.A. 26:4-131 et seq. and this subchapter, the Department incorporates by reference, as amended and supplemented, the following documents in this subchapter:

1. The 2001 Immunization Registry Minimum Functional Standards (hereinafter Functional Standards), which are available through the Centers for Disease Control and Prevention, National Center for Immunization and Respiratory Diseases, Data Management Division, Systems Development Branch, Registry Support Team, Immunization Registry Clearinghouse, 1600 Clifton Road, NE, MailStop E-62, Atlanta, GA 30333, telephone (800) 799-7062 or (404) 639-8570 or available online at <http://www.cdc.gov/vaccines/programs/iis/stds/min-funct-std-2001.htm>;

2. The Implementation Guide for Immunization Data Transactions using Version 2.3.1 of the Health Level Seven (HL7) Standard Protocol (June 2006) (hereinafter Implementation Guide for Immunization Data Transactions), which is available through the Centers for Disease Control and Prevention, National Center for Immunization and Respiratory Diseases, NIP Public Inquiries Mailstop E-05, 1600 Clifton Rd. NE, Atlanta, GA 30333, telephone (800) 232-4636 or (404) 639-8245, or available online at

<http://www.cdc.gov/vaccines/programs/iis/stds/downloads/hl7guide.pdf>;

3. The Recommended Immunization Schedules for Persons Aged 0 – 18 Years – United States, 2008 created through the collaboration of the Centers for Disease Control and Prevention’s Advisory Committee on Immunization Practices, the American Academy of Family Physicians, and the American Academy of Pediatrics, which is available through a written request to the VPDP mailing address or online at <http://www.cdc.gov/vaccines/recs/schedules/default.htm>;

4. The Recommendations for Preventive Pediatric Health Care (RE9535) commonly known as “the periodicity schedule,” developed by the American Academy of Pediatrics and, which is available through the American Academy of Pediatrics, AAP Policy, 141 Northwest Point Blvd, Elk Grove Village, IL 60007-1098 or online at <http://aappolicy.aappublications.org/cgi/content/full/pediatrics;105/3/645>; and

5. The Immunization Registry Certification: Recommendation of the National Immunization Program’s Technical Working Group (TWG) (June 4, 2002) (hereinafter IRC), which is available through the Centers for Disease Control and Prevention, National Center for Immunization and Respiratory Diseases, Data Management Division, Systems Development Branch, Registry Support Team, Immunization Registry Clearinghouse, 1600 Clifton Road, NE, Mail Stop E–62, Atlanta, GA30333, telephone

(800) 799-7062 or (404) 639-8570 or available online at

http://www.cdc.gov/vaccines/programs/iis/stds/downloads/certif_rec.pdf.

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

1. Enrollment Request for New NJIIS Site (Appendix A) is a form required of new sites in order to enroll as a NJIIS site, become an authorized user, and obtain access to the NJIIS, and is available for online enrollment at <http://njiis.nj.gov/njiis/html/forms.html>;

2. User Enrollment and Training Request (Appendix B) is the form required of a designated agent of a NJIIS site in order to obtain appropriate access to the NJIIS and to schedule training, and is available for online enrollment at <http://njiis.nj.gov/njiis/html/forms.html>;

3. User Confidentiality Agreement (Appendix C) is the agreement to maintain confidentiality of the NJIIS information of all registrants that is required of all authorized users;

4. Request for Change of User Security Authorization/Request for Password Reset (Appendix D) is the form required to change or withdraw a designated agent's access level or password;

5. NJIIS Informational Brochure (Appendix E) is the brochure created by the VPDP that describes the following:

- i. The purposes and uses of the NJIIS;
- ii. The personal and medical information contained within the NJIIS;

iii. Persons and agencies with access to NJIIS records;

iv. Procedures to enroll in and disenroll from the NJIIS;

v. Procedures to obtain a copy of a NJIIS immunization record or to seek amendment of information contained in a NJIIS immunization record;

and

vi. The right of a parent of a minor registrant, or a registrant if 18 years of age or over, to decline to participate in the NJIIS or to disenroll at any time;

6. Consent to Participate (Appendix F) is the form required of a parent of a minor registrant or a registrant, if 18 years of age or over, in order to enroll in the NJIIS if the registrant was not automatically enrolled pursuant to N.J.A.C. 8:57-3.12(a);

7. Declination of Newborn Automatic Enrollment (Appendix G) is the form required of a parent of a minor born on or after January 1, 1998, to indicate refusal to participate in the NJIIS pursuant to N.J.A.C. 8:57-3.12(a);

8. Request for Change to NJIIS Immunization Record (Appendix H) is the form required of a parent of a minor registrant or a registrant, if 18 years of age or over, in order to request an amendment to information contained in the registrant's NJIIS immunization record;

9. Request for Copy of NJIIS Immunization Record (Appendix I) is the form required of a parent of a minor registrant or a registrant, if 18

years of age or over to receive or have a copy of the immunization record sent to a specified individual or entity; and

10. Registrant Withdrawal From NJIIS (Appendix J) is the form used by a parent of a minor registrant or a registrant if 18 years of age or over, to disenroll from the NJIIS.

(c) All of the forms in (b) above are available by written request to the VPDP mailing address or online through the NJIIS webpage or the Department's Forms webpage at <http://web.doh.state.nj.us/forms/>.

8:57-3.3 Definitions

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

“Administrator” means the individual interested in enrolling his or her eligible entity in the NJIIS as a NJIIS site.

“Authorized user” means any health care provider, child care center, school, college or university, health benefits plan, billing and practice management vendor, State public health or social services program, local health agency or designated agents thereof, authorized pursuant to N.J.S.A. 26:4-134(c) and (g) and N.J.A.C. 8:57-3.9 to submit information to, receive information from, or access or review information contained in the NJIIS.

“Billing vendor” means an entity that a health care provider or health care practice contracts with in order to prepare invoices, claims, or statements of services performed by the provider or practice and submit them to a third party for payment or reimbursement.

“Biological” means a medicinal compound prepared from living organisms and their products such as Hepatitis B Immune Globulin (HBIG), which is routinely administered shortly after birth to a newborn of a mother diagnosed with infectious hepatitis B virus to prevent the transmission of the virus to the newborn.

“Birth center” shall have the meaning provided at N.J.A.C. 8:43G-19.1(b).

“Birthing facility” means a health care facility that provides birthing and newborn care services and includes birth centers.

“Collaborating public health programs” means those programs within the Department who have written agreements to exchange health screening and immunization data with the NJIIS, consistent with the stated purposes of this chapter.

“College” shall have the meaning provided at N.J.A.C. 9A:1-1.2.

“Designated agent” means a person to whom a site administrator has delegated responsibilities pursuant to N.J.A.C. 8:57-3.8(b) to submit information to, receive information from, or access or review information contained in the NJIIS.

“Electronic birth certificate” or “EBC” shall have the meaning provided at N.J.A.C. 8:19-1.1.

“Health care provider” means a health care facility licensed pursuant to N.J.S.A. 26:2H-12 or a health care professional who is directly involved in the provision of healthcare services and whose practice is regulated pursuant to Title 45 of the New Jersey Statutes (N.J.S.A. 45:1 et seq.) and State professional board rules, who in the course and scope of work duties, independently or under the supervision of the appropriate authority, administers vaccinations.

“Health benefits plan” means an insurance company, a health maintenance organization, or another organization that pays or reimburses a provider for immunizations administered and includes Medicaid and NJ FamilyCare.

“Health employer data information set” or “HEDIS” means the measurement tool created by the National Committee for Quality Assurance to collect data about the quality of care and services provided by health plans.

1. HEDIS is available for purchase through the National Committee for Quality Assurance, 2000 L St. NW, Suite 500, Washington, DC 20036, telephone (888) 275-7585 or (202) 955-3500 or online at <https://inetshop01.pub.ncqa.org/Publications/default.asp>.

“Local health agency” shall have the meaning provided at N.J.A.C. 8:52-2.1.

“Local Information Network and Communications System” or “LINCS” shall have the meaning provided at N.J.A.C. 8:52-2.1.

“Maternal and Child Health Consortia” or “MCHC” shall have the meaning provided at N.J.A.C. 8:33C-1.2.

“Minor” means a person that is under the age of 18.

“Newborn” means a child from birth up to and including 30 days of age.

“NJ FamilyCare Program” shall have the meaning provided at N.J.A.C. 10:49-1.3.

“NJ Medicaid Program” means the health insurance program administered by the Division of Medical Assistance and Health Services in the Department of Human Services that provides medical assistance to certain persons with low income and limited resources as authorized under Title XIX (Medicaid) of the Social Security Act.

“NJIS” means the New Jersey Immunization Information System operated by the Vaccine Preventable Disease Program within the Department’s Public Health Service Branch, Communicable Disease Service and established pursuant to N.J.S.A. 26:4-131 et seq. and this subchapter.

“NJiIS immunization record” means a paper or electronic copy 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 which is not a part of a child’s educational record.

“NJiIS site” means an entity such as a health care provider, child care center, school, college or university, health benefits plan, billing and practice management vendor, State public health program, State or county social services program, or local health agency that has enrolled with the NJiIS as an authorized user pursuant to N.J.A.C. 8:57-3.8(a).

“NJiIS webpage” means the webpage of the NJiIS available at <http://njiis.nj.gov/njiis>.

“Parent” means a person with legal custody of a child and includes a child’s biological parent, stepparent, adoptive parent, legal guardian, or other person legally responsible for the health and well-being of a child.

“Practice management vendor” means a company that develops and sells information technology electronic applications or software, which primarily focuses on patient medical records.

“Primary health care provider” means a health care provider that supervises, coordinates, and provides basic medical care for a registrant and maintains continuity of care.

“Registrant” means an individual whose demographic, immunization, and preventive health screening information is entered into the NJIIS.

“Responsible person” means an owner, chief executive officer, or other similarly identified person of a NJIIS site who possesses the authority to bind the site legally to the provisions of the User Confidentiality Agreement, available at Appendix C.

“Site administrator” means the person at a NJIIS site assigned to coordinate the NJIIS onsite and accept official documents regarding the NJIIS.

“Tracking and reminder or recall module” means the subsystem within the NJIIS designed to prompt an authorized user with access to this module, that has elected to use this module, to perform outreach to a parent of a minor registrant, or a registrant if 18 years of age or over, to foster the completion of an immunization series or the conduct of preventive health screenings in a timely manner.

“University” shall have the meaning provided at N.J.A.C. 9A:1-1.2.

“Vaccine” means an agent composed of biologically-derived and manufactured substances, which is licensed to be administered to persons in order to actively evoke an immune response to prevent serious illnesses associated with specific pathogens.

“Vaccines for Children Program” or “VFC” means the Federally funded and State-controlled program that provides free vaccines for eligible children zero through 18 years of age, established pursuant to 42 U.S.C. §1396s and operated through the Department’s Vaccine Preventable Disease Program.

“VPDP” means the Vaccine Preventable Disease Program within the Department responsible for administering and overseeing the operations of the NJIIS.

“VPDP mailing address” means the following address for the Department’s Vaccine Preventable Disease Program to which anyone may mail a written request for information pertaining to the NJIIS: Department of Health and Senior Services, New Jersey Immunization Information System, Vaccine Preventable Disease Program, PO Box 369, Trenton, NJ 08625-0369.

8:57-3.4 Confidentiality

(a) The Department shall keep confidential all NJIIS information that individually identifies a registrant.

1. The Department 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 registrants 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 Department may release NJIIS information that individually identifies a registrant or a NJIIS site to State or federal law enforcement agencies or agencies having investigatory authority, in cooperation with investigations of fraud or abuse, or as required for public health purposes; and

4. 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 N.J.A.C. 8:57-3.19(c).

(b) All NJIIS sites and authorized users shall keep medical and personal information contained in the NJIIS confidential pursuant to the terms of the User Confidentiality Agreement, available at Appendix C, and consistent with State and Federal law.

(c) Health benefits plans may request from the Department the NJIIS immunization records of their prior members or beneficiaries that are registrants 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 names and birthdates of the prior members or beneficiaries to the VPDP mailing address.

8:57-3.5 Administration

(a) The Department's Vaccine Preventable Disease Program (VPDP) is responsible for the administration of the NJIIS.

i. The VPDP shall ensure that the NJIIS conforms to the twelve technical functional standards for immunization registries as outlined in the 2001 Immunization Registry Minimum Functional Standards.

(b) The VPDP designates the local MCHC to coordinate the enrollment, training, and quality assurance components of the NJIIS, which requires the comparison of immunization information contained within the registrant's medical record at the health care provider's site to the immunization information documented in the NJIIS, under the supervision of the VPDP.

1. In the event that the VPDP designates another organization to coordinate the enrollment, training, and quality assurance components of the NJIIS, the VPDP shall provide notice of such designation, including contact information for the newly designated organization, through any of the following methods:

i. A posting on the NJIIS website;

ii. Electronic distribution using the Department's Local Information Network and Communications System (LINCS); or

iii. Any other method reasonably calculated to inform those persons most likely to be affected by or interested in the designation.

2. The VPDP designated organization shall have the same role and obligations as the MCHC pursuant to this subchapter.

(c) A list of the MCHC contact persons and contact information is available by mailing a written request to the VPDP mailing address or online at the NJIIS webpage.

(d) The local MCHC offices shall have the responsibility in the enrollment process to:

1. Accept letters of interest from applicants, NJIIS enrollment forms, and user confidentiality agreements 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 the NJIIS as set forth in N.J.S.A. 26:4-132 and 134 and this subchapter;

2. Provide the mandatory NJIIS training for authorized users as set forth at N.J.A.C. 8:57-3.8(g); and

3. Issue a user identification for each authorized user that has completed the NJIIS training.

8:57-3.6 Eligibility to become an authorized user

(a) The following persons and entities are eligible to become authorized users:

1. Health care providers, primary health care providers, child care centers, schools, colleges, universities, health benefits plans, billing and practice management vendors, State public health or State social services programs, local health agencies, 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 Authorized user enrollment requirements

(a) To enroll as a 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 User Confidentiality Agreement, available at Appendix C, to the local MCHC office; and
3. Complete the mandatory NJIIS training as set forth at N.J.A.C.

8:57-3.8(g).

8:57-3.8 Authorized user applicant enrollment process

(a) The administrator of any prospective eligible entity wishing to enroll as a NJIIS site and as an authorized user shall submit to the local MCHC office, via mail, facsimile or electronic submission, an application package consisting of:

1. A statement of interest in enrolling in the NJIIS;
2. A completed Enrollment Request for New Site form, available at Appendix A; and
3. An original User Confidentiality Agreement, available at Appendix C, signed and dated by the responsible person.

(b) The site administrator of any enrolled site wishing to designate agents to access and utilize the NJIIS shall assist the designated agents in enrolling as authorized users by submitting to the local MCHC office, via mail, facsimile or electronic submission, an application package consisting of:

1. A statement of interest in enrolling in the NJIIS;
2. A completed User Enrollment and Training Request form, available at Appendix B, through which the administrator shall request the appropriate level of access for the designated agent, and
 - 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.

3. An original NJIIS User Confidentiality Agreement, available at Appendix C, for each designated agent individually signed and dated.

(c) The local MCHC offices shall enroll or deny enrollment of the prospective entity or designated agent as a NJIIS site and authorized user respectively based on:

1. Consistency between the entity's or designated agent's purposes in enrolling as a 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 access for each designated agent is appropriate as determined by the description of the designated agent's employment functions; and

4. Whether the entity or designated agent complies with the eligibility requirements set forth at N.J.A.C. 8:57-3.6.

(d) If the MCHC denies enrollment of an entity or designated agent, the MCHC shall notify the administrator of the decision in writing within 30 days of the date on which the MCHC makes the decision.

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 a 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 site administrator may request a change in an authorized user's access level or password reset by submitting a completed Request for Change of User Security Authorization/Request for Password Reset form, available at Appendix D, to the NJIIS Help Desk at the facsimile number indicated on the NJIIS webpage or to the local MCHC.

1. An authorized user may periodically change his or her password as prompted by the NJIIS.

(g) All enrolled authorized users, shall complete a mandatory NJIIS training conducted by a NJIIS certified trainer.

1. Each NJIIS certified trainer shall notify site administrators in writing of authorized users' completion of training.

8:57-3.9 Authorized user access to information

(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 FamilyCare 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) An authorized user attempting to obtain access to NJIIS information on a registrant that has withdrawn from the NJIIS will not be able to access the information and will receive a message indicating that the registrant withdrew from the NJIIS and the immunization information is not accessible.

(e) Anyone seeking technical information or online assistance may contact the NJIIS Help Desk at 1-800-883-0059 between 8am and 5pm, Monday through Friday or by email at helpdesk@doh.state.nj.us.

8:57-3.10 Authorized user withdrawal

(a) Any administrator or site administrator may withdraw or change an authorized user's access to the NJIIS at any time by submitting a completed Request for Change of User Security Authorization/Request for Password Reset form, available at Appendix D, to the NJIIS Help Desk at the facsimile number indicated on the NJIIS webpage or to the local MCHC.

(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 Informing parents

(a) The VPDP shall make available an NJIIS Informational Brochure, available at Appendix E.

(b) Birthing facilities shall complete the following process with regard to informing parents about the NJIIS:

1. Maintain written procedures to document and ensure each parent is provided a copy of 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 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) Health care providers providing medical care to a newborn or minor born after January 1, 1998, shall complete the following process with regard to informing parents about the NJIIS:

1. Record the provision of the NJIIS Informational Brochure to the 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 minor; or

3. Retain a copy of a completed Consent to Participate form available at Appendix F, in the permanent medical record of the newborn or minor.

8:57-3.12 Registrant enrollment

(a) Birthing facilities shall automatically enroll all newborns 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 Appendix G, which shall be noted on the EBC.

(b) When a newborn is enrolled, birthing facilities shall:

1. Record and report information about any vaccine or biological administered at the birthing facility on the EBC 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 to inform the parent about the NJIIS.

(d) 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 enrollment to any authorized user, excluding a billing vendor, health benefits plan, or practice management vendor; or
2. Submit a completed Consent to Participate form, available in Appendix F, to the VPDP at the VPDP mailing address.

(e) An authorized user, as described in (d)1 above, or the VPDP respectively, shall 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 (d) above no later than 30 days from the date of the request and provide the parent, or an adult registrant, with a NJIIS Informational Brochure.

(f) An adult registrant may enroll in the NJIIS, after receipt of an NJIIS Informational Brochure, available at Appendix E, by completing the process as set forth at N.J.A.C. 8:57-3.12(d).

1. Enrollment in the NJIIS shall not diminish the responsibility of a parent or an adult registrant, to comply with the immunization rules established at N.J.A.C. 8:57-4 and N.J.A.C. 8:57-6, as applicable.
2. A registrant who has previously declined participation in, or withdrawn from the NJIIS, in order to resume participation shall submit a completed Consent to Participate Form, available in Appendix F to the VPDP mailing address.

(g) 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.

(h) 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 N.J.A.C. 8:57-6.14 and 6.15.

8:57-3.13 Registrant access to information

(a) Any registrant or parent of a registrant, if he or she is a minor, shall have access to 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 an authorized user;

or

i. The authorized user may request verification of identification; and

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.

2. Submit a completed Request for Copy of NJIIS Immunization Record form, available at 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.

8:57-3.14 Registrant amendment of record

(a) Any registrant or parent of a registrant, if he or she is a minor, may request an amendment of demographic or medical information contained in the registrant's NJIIS record by completing the following:

1. Submit a request for an amendment of demographic information to an authorized user utilizing the Request for Change to NJIIS Immunization Record form, available at Appendix H, with appropriate documentation necessary to modify existing information contained in a NJIIS record; or

2. Submit a request for an amendment of 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 a 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) The VPDP may deny a request to amend medical information, upon determining that the information 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 or in part, the authorized user or VPDP respectively, shall:

1. Make the appropriate amendment to the registrant's information;

and

2. Inform the registrant of the acceptance of the request in accordance with (c) above.

(e) If the authorized user or VPDP denies the requested amendment, the authorized user or VPDP respectively, shall provide the registrant or parent of the registrant, if he or she is a minor, with a written denial pursuant to (c) above that contains the basis for denial and notification of the registrant's right to submit a written statement of reasonable length disagreeing with the denial.

(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) The VPDP shall make a notation in the registrant's NJIIS record under the NJIIS Notepad tab of the request for an amendment, the denial of the request, any written statement of disagreement, and any written statement of rebuttal.

(h) The authorized user or VPDP respectively shall maintain all documents related to the amendment of record process set forth in (a) through (f) above.

(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 Registrant withdrawal

(a) A registrant or parent of a registrant, if he or she is a minor, may withdraw from the NJIIS at any time by completing the following process:

1. Submit a completed Registrant Withdrawal from NJIIS form, available at Appendix J, to the VPDP at the VPDP mailing address.

i. The VPDP shall retain the copy of the 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 business days from the date of receipt of the request.

1. The VPDP shall deactivate the complete immunization record within the NJIIS and send a 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.

(c) A registrant, or parent of a registrant, if he or she is a minor may re-enroll the registrant in the NJIIS by completing the process established at N.J.A.C. 8:57-3.12.

8:57-3.16 Mandatory participation for health care providers

(a) Every health care provider administering vaccines to children less than seven years of age shall register as a NJIIS site and authorized user and commence online reporting of vaccinations prior to January 1, 2011, in compliance with this subchapter.

(b) Any health care provider that participates in the NJIIS shall report vaccinations of NJIIS registrants through the following methods:

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 NJIIS such as a health benefit plan, practice management vendor, or billing management vendor; or

4. An authorized user entering data manually for a NJIIS site directly into the NJIIS through an internet connection.

(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 shall report, update or verify as applicable, the following required data fields for the registrant within 30 days of vaccine administration:

1. Complete name;
2. Date of birth;
3. Ethnicity/Race;
4. Gender;
5. Address;
6. Name of responsible party and relationship;
7. Name of the vaccine administered;
8. Funding source of the vaccine administered; and

9. The month, day, and year the health care provider administered the vaccine.

(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 the administration of vaccines.

(f) To the extent the information is available, participating NJIIS health care providers may report the following to the NJIIS, in order to complete the registrant's immunization history:

1. Any doses of vaccinations previously administered to the registrant by the health care provider that may not have been reported to the NJIIS; or

2. Any doses of vaccinations previously administered to the registrant by a prior health care provider, for which there is documentation.

(g) Non-participating NJIIS health care providers may notify the VPDP of a potential error in the NJIIS record, if the health care provider believes any information is inaccurate or false by submitting a Request for Change to NJIIS Immunization Record form, available at Appendix H, to the VPDP at the VPDP mailing address.

8:57-3.17 Application of the NJIIS tracking/reminder recall function

(a) In order to utilize the functions of the NJIIS tracking and reminder/recall module, any authorized user with access to the module as set forth at N.J.A.C. 8:57-3.8(b), that has selected to use the module may:

1. Notify a registrant or parent of a registrant, if he or she is a minor, by telephone, mail, or personal contact about the registrant's current vaccination or preventive health screening status or about a vaccination or preventive health screening that is due or overdue according to:

i. The Recommended Immunization Schedules for Persons Aged 0 – 18 Years, applicable for that year; and

ii. The Recommendations for Preventive Pediatric Health Care (RE9535) commonly known as "the periodicity schedule."

(b) The registrant or parent of a registrant, if he or she is a minor, may decline participation in the NJIIS tracking and reminder/recall module by notifying the authorized user described in (a) above.

1. A registrant or parent of a registrant, if he or she is a minor that declines participation in the NJIIS tracking and reminder/recall module may participate in other functions of the NJIIS as set forth in this subchapter.

8:57-3.18 Acceptance of NJIIS record as evidence of immunization

Child care centers, schools, colleges, and universities in New Jersey shall accept a NJIIS immunization record, as an adequate form of required immunization documentation used to determine admission of a registrant to any of those institutions.

8:57-3.19 Data exchange

(a) Any authorized user reporting vaccinations pursuant to N.J.A.C. 8:57-3.16, 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.

1. The Department shall inform authorized users, as described in (a) above, of the secure electronic file format upon completion of the enrollment and training process established at N.J.A.C. 8:57-3.8.

(b) Health benefit plans, billing vendors, and practice management vendors should submit all vaccination and preventive health screening information to the NJIIS in accordance with the NJIIS interface file specifications.

1. The Department's Office of Information Technology Services (OITS) will distribute NJIIS interface file specifications to authorized users that will be made available on the NJIIS webpage at:

<https://njiis.nj.gov/njiis/jsp/uploadshots.jsp>; or

2. Interface file specifications may be requested by calling the NJIIS helpdesk at (800) 883-0059; and

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 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 health care oversight function if:

1. The receiving state or regional registry has confidentiality and security protections in place that are consistent with the protections of the NJIIS; and

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.

(d) To the extent that the Department permits the exchange of data contained in the NJIIS, the Department's data exchange policies will be consistent with the Implementation Guide for Immunization Data Transactions.

8:57-3.20 Reports

- (a) The Department may release summary statistical data and supporting narrative information collected from the NJIIS in an aggregate

form that does not identify an individual registrant 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 deemed “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 government records subject to public access or inspection within the meaning of N.J.S.A. 47:1A-1 et seq.

8:57-3.21 Authorized user immunity

(a) Any authorized user submitting, providing, or otherwise transmitting vaccine or preventive health screening information to the NJIIS in good faith to further the purposes of promoting public health, providing patient care, or fostering regulatory compliance, in accordance with the provisions of N.J.S.A. 26:4-131 et seq. and this subchapter, shall not be held liable for divulging confidential registrant information as set forth at N.J.S.A. 26:4-135(a).

1. The Department may request any authorized user accessing the NJIIS to provide supporting documentation that access is consistent with the authority set forth at N.J.A.C. 8:57-3.8 and 3.9.

(b) Any authorized user reporting, retrieving, or disclosing information relating to the NJIIS pursuant to N.J.S.A. 26:4-131 et seq. or this subchapter shall be immune from liability for any error or inaccuracy contained in the NJIIS information and any consequences thereof as set forth at N.J.S.A. 26:4-135(b).

8:57-3.22 Penalties

(a) Any authorized user that fails to comply with this subchapter or knowingly enters false information into the NJIIS shall be subject to suspension or revocation of access to the NJIIS.

(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 a 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 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.

8:57-3.23 Appeals

(a) An applicant that is denied enrollment as a NJIIS site or authorized user; or

(b) An authorized user whose access to the NJIIS has been suspended or revoked may file an appeal as set forth in (c) below.

(c) An applicant or authorized user wishing to submit an appeal made pursuant to (a) or (b) above shall:

1. Submit two written copies of the appeal to the Commissioner within 30 calendar days of the VPDP or MCHC issuance of a letter of denial of enrollment, or suspension or revocation of access to the NJIIS at the address provided in that letter; and

2. Include in the written appeal:

- i. A detailed description of the basis of the appeal;
- ii. A list of all factual and legal issues;
- iii. Citations to the applicable provisions of the NJIIS rules; and
- iv. Any supporting documentation.

(d) The Commissioner shall give consideration only to documentation submitted pursuant to the timeframe set forth in this section in deciding upon any of the appeal issues.

(e) Within 45 calendar days of the receipt of a written appeal, the Commissioner shall render detailed findings on the factual and legal issues presented.

(f) The Commissioner's written decision shall constitute the final agency adjudication.