NEW JERSEY

Birth Defects Surveillance System

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<tr>
<th>State</th>
<th>Statute/Rule</th>
<th>Language Specific to Surveillance System</th>
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<th>Research Authority</th>
<th>Consent Required?</th>
<th>Dissent Allowed?</th>
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<tr>
<td>NJ</td>
<td>STATUTE: Title 26, Chapter 8</td>
<td>26:8-40.22 Confidential reports of abortions of fetus with or infant affected by birth defect or severe neonatal jaundice. a. The Commissioner of Health and Senior Services, in consultation with the Public Health Council, shall require the confidential reporting to the Department of Health and Senior Services of all cases where an infant is diagnosed with severe hyperbilirubinemia, and where a pregnancy results in a naturally aborted fetus or infant affected by a birth defect, and an electively aborted fetus that exhibits or is known to have a birth defect after 15 weeks of gestation. The reporting requirement shall apply to all infants from birth through five years of age. b. The Commissioner of Health and Senior Services shall determine the health care providers and facilities which shall be required to report all birth defects and all cases of severe hyperbilirubinemia, the types of conditions or defects that shall be reported, the type of information that shall be contained in the confidential report and the method for making the report. In reports concerning all fetuses with anomalies, the name of the mother shall not be submitted.</td>
<td>26:8-40.24. Nonliability for divulging confidential information. No individual or organization providing information to the Department of Health in accordance with this act shall be deemed to be or held liable for divulging confidential information. § 8:20-1.2 Reporting requirements (a) A health care professional shall report any child who is born to a resident of the State of New Jersey, or who becomes a resident of the State prior to and through five years of age, and who is diagnosed as having a defect either at birth or any time through the fifth year of life to the Department, Special Child Health and Early Intervention Services Program as follows: … (b) Clinical laboratories shall report…any newborn…who has a total serum bilirubin (TSB) of 25 milligrams per deciliter (mg/dl) or greater, or who receives an exchange transfusion…. (c) Any live born child with a birth defect who has not been previously registered and has expired shall be reported. Such reports shall indicate that the child has expired. (d) The administrative officer of every health care facility shall be responsible for establishing the reporting procedures for that facility. The reporting procedures must insure that every infant who has a birth defect shall be reported to the Department. All presumptive, tentative, pending, or rule out diagnoses will be reported at the time of discharge, if the child will be diagnosed at a later time or if test results are pending. (e) Every health care professional who treats, manages or who has any medical responsibility for, diagnoses or confirms birth defects shall report to the Department each child diagnosed as having a birth defect not known to be previously reported. (f) The director of every clinical laboratory shall report to the Department results of postmortem examination from any infant indicating the existence of a birth defect, not known to be previously reported.</td>
<td>§ 8:20-1.2 Reporting requirements …(j) When a child is registered, the Department shall inform the parent or legal guardian of the registration. (k) Every health care facility and independent clinical laboratory shall allow access to, or provide necessary information on children with birth defects and other patients specified by characteristics for research studies conducted by the and which have been approved by the after appropriate review for assuring protection of human subjects by the Department's Institutional Review Board. This shall include patients who came under the care of the health facility prior to March 4, 1985.</td>
<td>NO</td>
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## Cancer Surveillance System

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<td>NJ</td>
<td>STATUTE: NIPS Title 26, Chapter 2 RULE: NJAC Title 8, Chapter 57A</td>
<td>26:2-105 Establishment, maintenance of State cancer registry. 2. The Department of Health and Senior Services shall establish and maintain an up-to-date registry which shall include a record of cases of cancer and specified cases of tumors or precancerous disease that occur in New Jersey, and such information concerning these cases as it shall deem necessary and appropriate in order to conduct thorough and complete epidemiologic surveys of cancer and cancer-related diseases in this State and to apply appropriate preventive and control measures.</td>
<td>26:2-106 Reports; rules, regulations; enforcement. 3. a. The Commissioner of Health and Senior Services, in consultation with the Public Health Council, shall require the reporting of cases of cancer and other specified tumors and precancerous diseases, and the submission of such specified additional information on reported cases or control populations as he deems necessary and appropriate for the recognition, prevention, cure or control of such diseases… c. All abstracting work performed by a health care facility in accordance with this section shall be performed by a certified tumor registrar. d. (1) The Department of Health and Senior Services shall contract out its registry services to health care facilities which lack adequate internal capabilities to report cases on a timely basis, as provided in the regulations adopted pursuant to this section. Such health care facilities shall reimburse the department for services rendered. (2) If a health care facility fails to correct deficiencies in its reporting that are discovered on audit by the Department of Health and Senior Services within 30 days, the department will conduct the appropriate registrar activities and charge the facility for all costs related to its services… f. (1) A health care facility, health care provider or health insurer that fails to comply with the provisions of this section shall be liable to a penalty of up to $500 per unreported cancer case. (2) A health care facility that fails to report cases of cancer electronically, as required by regulation, shall be liable to a penalty not to exceed $1,000 per business day…</td>
<td>26:2-105 …The Department of Health and Senior Services…shall include a record of cases of cancer and specified cases of tumors or precancerous disease that occur in New Jersey, and such information concerning these cases as it shall deem necessary and appropriate in order to conduct thorough and complete epidemiologic surveys of cancer and cancer-related diseases in this State… § 8:57A-1.10 Access to information and record …(b) Every health care facility, independent clinical laboratory, physician, dentist, or other health care provider who diagnoses or provides treatment for cancer patients and health care insurers and other third party health care payers providing benefit plans to residents of the State shall permit representatives of the access to information or provide necessary information on specified cancer patients and other patients specified by characteristics for research studies related to cancer etiology, prevention, and control which are conducted by the Department (1.) The Department’s designated Institutional Review Board shall: (i) Review the studies to assure protection of human subjects; and (ii) Approve or disapprove the studies, as appropriate, based on the outcome of the review. (2.) This access or provision of information shall include patients who came under the care of the health care facility, physician, dentist or other health care provider prior to November 18, 1977.</td>
<td>NO</td>
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Newborn Genetic Testing & Surveillance System

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<tr>
<td>NJ</td>
<td>STATUTE: NJPS, Title 26, Chapter 2</td>
<td>26:2-111. Testing of infants for biochemical disorders. All infants born in this State shall be tested for hypothyroidism, galactosemia and phenylketonuria. The Commissioner of Health shall issue regulations to assure that newborns are so tested in a manner approved by the commissioner. The commissioner shall ensure that treatment services are available to all identified individuals...The commissioner may also require testing of newborn infants for other preventable biochemical disorders if reliable and efficient testing techniques are available. If the commissioner determines that an additional test shall be required, 90 days prior to requiring the test he shall advise the President of the Senate, Speaker of the General Assembly and chairmen of the standing reference committees on Revenue, Finance and Appropriations and Institutions, Health and Welfare of his determination. The commissioner shall provide a program of reviewing and following up on positive cases in order that measures may be taken to prevent mental retardation or other permanent disabilities. Information on newborn infants and their families compiled pursuant to this section may be used by the department and agencies designated by the commissioner for the purposes of carrying out this act, but otherwise the information shall be confidential and not divulged or made public so as to disclose the identity of any person to which it relates, except as provided by law... [emphasis added]</td>
<td>26:2-111. ...The provisions of this section shall not apply if the parents of a newborn infant object to the testing on the grounds that it would conflict with their religious tenets or practices. 26:2-111.1. Option of additional screening for disorders in infants required; cost... (2) A health care provider shall give an infant's parent or guardian a hard copy of the information prepared pursuant to paragraph (1) of this subsection and provide the parent or guardian with a reasonable opportunity to read the information when giving the parent or guardian the option of consenting to the performance of testing pursuant to subsection a. of this section.</td>
<td>§ 8:18-1.14 Provision of notice of availability of supplemental newborn screening; Acknowledgement; retention (a) A health care provider who provides care to an expectant parent or to a newborn infant shall, as applicable with respect to the expectant parent or the parent of the newborn (hereinafter both referred to as the &quot;parent&quot;): 1. Provide the Notice to the parent; 2. Provide the parent with a reasonable opportunity to read the Notice; 3. Make reasonable efforts to ensure that the parent understands the information provided in the Notice; 4. Obtain the signature of the parent on the Acknowledgment; 5. Retain the executed Acknowledgement in the patient's medical record; and 6. Permit the parent to keep the Notice.</td>
<td>NO</td>
<td>YES</td>
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Updated August 2012. All state statutes and department rules originally accessed online July/Aug 2008. Statute/Rule data not inclusive. For comprehensive or updated language, access complete statute and rules online, at local library or through the state legislature. www.cchffreedom.org
1. At minimum, the policies and procedures required pursuant to (a) above shall address memorializing the time and date of receipt of test kits from parents, obtaining parents' informed consent to the collection of specimens in accordance with the instructions in the test kit, and ensuring that appropriate personnel execute or arrange for the execution of such forms and collect or arrange for the collection of such specimens, and otherwise take such steps that are within the health care facility's ability as may be required by a qualified laboratory to assist in and enable the performance of supplemental newborn screening in accordance with instructions accompanying a test kit, subject to applicable standards of care depending upon the particular health situations of newborns from whom supplemental screening specimens are to be collected.

§ 8:18-1.10. Responsibilities of the Follow-up Program

(a) The Follow-up Program shall:

1. Make every reasonable effort to follow abnormal test results to case disposition as specified in the Follow-up Program Procedures Manual;
2. Assist families of children with abnormal test results to access health care as necessary;
3. Identify and maintain contact with medical consultants (neurologists, endocrinologists, geneticists, hematologists) for each disease tested;
4. Identify treatment resources to families and assure that they are receiving care;
5. Provide educational support for activities carried out under this rule; and
6. In conjunction with the testing laboratory:
   i. Monitor compliance with this subchapter;
   ii. Identify problems in compliance and assist in their remediation; and
   iii. Prepare and distribute an annual report, to include outcome data, descriptive statistics, program evaluation and recommendations.

(b) In case of refusal to test pursuant to (a) above, the chief executive officer or responsible physician or birth attendant or home health agency shall assure that documentation of refusal to test becomes part of the infant's permanent medical record.

(c) The chief executive officer or responsible physician or birth attendant or home health agency shall assure that a copy of documentation of refusal to test is forwarded to the testing laboratory.

26:2-111.1 Option of additional screening for disorders in infants required; cost.

1. a. A health care provider shall give an infant's parent or guardian the option of consenting to the performance of testing by qualified laboratories for disorders in infants for which testing is not required pursuant to P.L.1977, c.321 (C.26:2-110 et seq.), on a form and in a manner prescribed by the Commissioner of Health and Senior Services. …
### Vaccination Surveillance System

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<td>NJ</td>
<td>STATUTE: NJPS Title 26, Chapter 4 -131 et seq. RULE: NJAC 8:57: 3.1 – 3.23 plus Appendices A - J</td>
<td>26:4-134 Statewide automated and electronic immunization registry. 4. a. There is established a Statewide automated and electronic immunization registry, to be designated as the New Jersey Immunization Information System, in the Department of Health and Senior Services. The registry shall be designed to serve as a single repository of immunization records to aid, coordinate and help promote effective and cost-efficient disease screening, prevention and control efforts in the State... A registrant, or the registrant's parent or legal guardian if the registrant is a minor, shall have access to the registrant's immunization and other preventive health screening information in the registry. d. The information contained in the registry shall be used for the following purposes: (1) to help ensure that registrants receive all recommended immunizations in a timely manner by providing access to the registrants' immunization records; (2) to help improve immunization rates by providing notice to registrants of overdue or upcoming immunizations; and (3) to help control communicable diseases by assisting in the identification of persons who require immediate immunization in the event of a vaccine-preventable disease outbreak.</td>
<td>NJIS Decline to Enroll Newborn: <a href="http://www.state.nj.us/health/forms/imm-32.pdf">http://www.state.nj.us/health/forms/imm-32.pdf</a></td>
<td>NO</td>
<td>YES</td>
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26:4-135 Immunity from liability. 5. Notwithstanding any other provision of this act to the contrary, a person or entity, who is authorized by the commissioner to report, receive or disclose information relating to the registry pursuant to this act, shall be immune from liability for: a. reporting information to, receiving information from, or disclosing information received from, the registry in accordance with the provisions of this act or any regulation adopted pursuant thereto; and b. any error or inaccuracy in the information that is reported to, received from, or disclosed after receipt from, the registry in accordance with the provisions of this act or any regulation adopted pursuant thereto, and any consequence of that error or inaccuracy.

26:4-138 Certain transmissions of information permitted. 8. The provisions of this act shall not prohibit the transmission or exchange of immunization information from other government database systems, immunization registries of other states or similar regional registries officially recognized by those states, health maintenance organizations or health benefits plans, health insurance companies, practice management or billing vendors, or other similar databases containing immunization histories, if the transmission is in accordance with the provisions of this act and other relevant State and federal laws and regulations.
e. The authentic immunization and other preventive health screening record of a child, which shall consist of a paper or electronic copy of the registry entry that is a true and accurate representation of the information contained therein, obtained from the registry shall be accepted as a valid immunization and preventive health screening record of the registrant for the purpose of meeting immunization and preventive health screening documentation requirements for admission to a school, college or licensed child care center.

g. An authorized user granted access as provided in subsection e. of this section shall only access information in the registry on a specific patient or client who is presently receiving services, is under the user's care or is within the applicable governmental health authority's jurisdiction.

h. An agency, organization or other entity authorized to access information in the registry shall not use any report made by a health care provider pursuant to this act in any punitive manner against the provider.

§ 8:57-3.11 Informing parents

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

... 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.

(e) 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:

... 2. Make a written notation, if the parent declines to participate in the NJIIS, in the permanent medical record of the newborn or minor.

§ 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 an 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 subchapter 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), 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.
§ 8:57-3.1 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 (NJIIIS) 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 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) This subchapter applies to all authorized users and registrants.

§ 8:57-3.19 Data exchange …(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: …

§ 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.
§ 8:57-3.16 Mandatory participation for health care providers
(a) Every health care provider administering vaccines to children less than seven years of age shall register as an NJIIS site and authorized user and commence online reporting of vaccinations prior to December 31, 2011, in compliance with this subchapter. …

§ 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 an NJIIS site and authorized user and commence online reporting of vaccinations prior to December 31, 2011, in compliance with this subchapter. …

(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. …

§ 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 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 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.