

## DELAWARE

### Birth Defects Surveillance System

State	Statute/Rule	Language Specific to Surveillance System	Data Sharing	Research Authority	Consent Required?	Dissent Allowed?
DE	<p>STATUTE: Delaware Code, Title 16, Chpt 2, Subchpt I §201</p> <p>RULE: 6 DE Reg. 1211 (3/1/03 Final)</p>	<p><b>Subchapter I. Congenital Disabilities Surveillance, Registration and Treatment Program</b></p> <p><b>§201. Purpose:</b> The intent of the General Assembly is to ...require the establishment and maintenance of a congenital disabilities surveillance system and registry for the State. <b>(1)</b> Surveillance system and registry. -- Responsibility for establishing and maintaining the system and registry is delegated to the Department of Health and Social Services, along with the authority to exercise certain powers to implement the system and registry. To ensure an accurate and continuing source of data concerning congenital disabilities, the General Assembly by this subchapter requires certain health care practitioners and all hospitals and clinical laboratories to make available to the Department of Health and Social Services information contained in the medical records of patients who have a suspected or confirmed congenital disability diagnosis. All confirmed congenital disabilities shall be classified and coded using the medically recognized system of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM), as well as the 6-digit modified British Pediatric Association system (BPA/ICD-9), and all subsequent revisions to these publications which are used by the Centers for Disease Control and Prevention. It is intended that the product of these efforts will be a central data bank of accurate, precise and current information regarding all congenital disabilities diagnosed or treated, or both, in this State. (71 Del. Laws, c. 86, § 1; 71 Del. Laws, c. 286, § 3.)</p>	<p><b>§ 204. Confidentiality of reports.</b></p> <p><b>(a)</b> ...Patient-identifying information may be exchanged among authorized agencies as approved by the Department and upon receipt by the Department of satisfactory assurances by those agencies of the preservation of the confidentiality of such information.</p> <p><b>§ 203. (b)</b> The provisions of this subchapter and any rules or regulations issued pursuant to this subchapter shall not apply to any person or private institution that, as an exercise of religious freedom, treats the sick or suffering by spiritual means through prayer alone.</p>	<p><b>§203. Birth Defects Surveillance and Registry Program.</b> (a)(2)a. ...Specified information shall be deemed necessary and appropriate to accomplish the purpose of this subchapter and in accordance with the recommendations from the Centers for Disease Control and Prevention, for the following reasons: 1. To identify risk factors for congenital disabilities; 2. To investigate the causes and prevalence of congenital disabilities; 3. To develop preventive strategies to decrease occurrences of congenital disabilities; 4. To analyze incidences, prevalence and trends of congenital disabilities through epidemiological studies; or 5. To investigate the morbidity and mortality rates resulting from congenital disabilities...</p> <p><b>4.1.</b> Agencies will maintain the confidentiality of any information exchanged for the purpose of delivery of program services, evaluation, early intervention and epidemiological investigation.</p>	NO	YES

		<p><b>§ 202. Definitions.</b> The following words, terms and phrases, when used in this subchapter, shall have the meanings ascribed to them in this section, except where the content clearly indicates a different meaning. (1) "Department" means the Department of Health and Social Services. (2) "Congenital disability" means any structural or biochemical abnormality, regardless of cause, diagnosed at any time before or after birth that requires medical or surgical intervention or that interferes with normal growth or development. (3) "Surveillance" means the process of identifying and investigating congenital disabilities in children under age 5. (4) "Registry" means a central data bank containing collected, classified, coded and stored data relating to congenital disabilities in children under age 5. (71 Del. Laws, c. 86, § 1; 71 Del. Laws, c. 286, § 3.</p> <p><b>§ 203. Birth Defects Surveillance and Registry Program.</b> The Department may adopt, promulgate, amend and repeal any rules and regulations necessary to accomplish the purpose of this subchapter... (1) The establishment and maintenance of an up-to-date registry that shall document every diagnosis or treatment, or both, of any congenital disability in any child under age 5 in this State;</p> <p><b>1.0 Purpose...</b> 1.2 The purpose of the Birth Defects Registry is to provide information to Public Health officials as to the existence of previously unrecognized health and environmental hazards, help prevent certain birth defects and ultimately decrease the infant mortality rate. ... 1.4 The Birth Defects Registry will be a component of the Newborn Screening Case Management System, including metabolic and hearing screening. All results of metabolic and hearing screens will become part of the screening record. Tracking and follow-up of incomplete and abnormal cases will be followed by the Division of Public Health Newborn Screening Program.</p>	<p><b>4.0 Confidentiality of Reports.</b> 4.1 No report of a diagnosis or treatment of a birth defect shall be disclosed in such a way as to identify the child who is the subject of the report, or as to identify the child's family. However, patient-identifying information may be exchanged among authorized agencies as approved by the Department and upon receipt by the Department of satisfactory assurances by those agencies of the preservation of the confidentiality of such information....</p> <p>...[4.3] No individual or organization providing information pursuant to these regulations shall be held liable for divulging such information to the Division.</p>	<p><b>4.0 Confidentiality of Reports</b> [4.2] Any parent, custodian or guardian of any infant having any birth defect may refuse disclosure to the surveillance system and registry of the infant's name and identifying information on the grounds that such birth defect identification is contrary to the religious tenets and practices of the infant's parent, custodian or guardian.]</p>		
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**Cancer Surveillance System**

State	Statute/Rule	Language Specific to Surveillance System	Data Sharing	Research Authority	Consent Required?
DE	<p>STATUTE: Title 16, Chapter 32, §3201 to §3208</p> <p>RULE: D.A.C. 4201</p>	<p><b>§ 3201. Short title.</b> This chapter may be cited as the Delaware Cancer Control Act.</p> <p><b>§ 3202. Purpose.</b> The intent of the General Assembly is to require the establishment and maintenance of a cancer registry for the State. This responsibility is delegated to the Department of Health and Social Services, along with the authority to exercise certain powers to implement this requirement. To ensure an accurate and continuing source of data concerning cancer and certain specified tumors of a benign nature, the General Assembly by this chapter requires certain health care practitioners and all hospitals, clinical laboratories and cancer treatment centers within the State to make available to the Department of Health and Social Services information contained in the medical records of patients who have cancer or tumors of a benign nature. It is intended that the product of these efforts will be a central data bank of accurate, precise and current information regarding the subject diseases.</p> <p><b>§ 3204. Cancer registry.</b> The Department shall adopt, promulgate, amend and repeal any rules and regulations that are consistent with law relative to this chapter and necessary to achieve the purpose and requirements of this chapter. These rules and regulations shall include provisions for: <b>(1)</b> The establishment and maintenance of an up-to-date registry that shall document every occurrence of cancer and of benign tumor in this State; <b>(2)</b> The establishment of a procedure for reporting to the Department, within 180 days of initial diagnosis or treatment, every occurrence of cancer and of benign tumor in this State. Such procedure shall include the reporting of specified information that the Department deems necessary and appropriate for the recognition, prevention, control or cure of cancer and benign tumors, and shall minimally include the reporting requirements of the National Cancer Data Base established by the American College of Surgeons, along with information regarding the patient's length of residency in Delaware, primary residential address in Delaware and the location and nature of the patient's primary past employment.</p>	<p><b>§ 3204. Cancer Registry . . .</b>(4) The establishment of a procedure to obtain follow-up information from those required to report occurrences of cancer and benign tumors pursuant to this chapter. Any follow-up information deemed necessary by the Department shall be submitted to the Department at least 1 time each year by those required to report occurrences of cancer and benign tumors.</p> <p><i>This chapter and any rules or regulations issued pursuant to this chapter shall not apply to any person or private institution that, as an exercise of religious freedom, treats the sick or suffering by spiritual means through prayer alone. [emphasis added]</i></p> <p><b>§ 3205. Confidentiality of reports. (a)</b> Any report of an occurrence of cancer or benign tumor made pursuant to this chapter shall not be divulged nor made public in any way that might tend to disclose the identity of the person to whom it relates. However, patient-identifying information may be exchanged among cancer control agencies as authorized by the Department and upon receipt by the Department of satisfactory assurances by those agencies of the preservation of the confidentiality of such information. <b>(b)</b> No individual or organization providing information to the Department in accordance with this chapter shall be deemed to be, or held liable for, divulging confidential information.</p> <p><b>4201. 5.0 Retention of Required Information</b> A health care provider who is treating a patient who has been diagnosed with cancer or a benign tumor shall ask that patient to fill out a form requesting disclosure of the address at which the patient has lived for the longest period of time in his or her life, the occupation at which the patient has worked for the longest period of time in his or her life, and the name and address of the employer at the occupation where the patient has worked for the longest period of time. The health care provider shall retain the form required by this Section with the patient's medical records pursuant to generally accepted protocol for the retention of patient medical records. The health care provider shall include the information from the form required by this Section with information it submits pursuant to Section 3 of these regulations. The Department shall provide a form for use in complying with this Section.</p>		NO

**Newborn Genetic Testing & Surveillance System**

State	Statute /Rule	Language Specific to Genetic Testing and Surveillance	Exemption	Research Authority	Consent Required?	Dissent Allowed?
DE	16 D.C. §122 (1) and 16 DC §122(3)(h)  <b>RULE:</b> D.A.C. 4107	<p><b>§ 122. Powers and duties of the Department of Health and Social Services.</b> The Department shall have the following general powers and duties: <b>(1)</b> Supervision of all matters relating to the preservation of the life and health of the people of the State...<b>(3)</b> Adopt, promulgate, amend, and repeal regulations consistent with law, which regulations shall not extend, modify or conflict with any law of this State or the reasonable implications thereof, and which shall be enforced by all state and local public health officials, to:...<b>h.</b> Control the practice of non-nurse midwives including the issuance of permits and protect and promote the health of all mothers and children...</p> <p><b>4107. Testing of Newborn Infants For Metabolic, Hematologic and Endocrinologic Disorders.</b> Under the authority granted to the Department of Health and Social Services, Division of Public Health under 16 Del.C. §122(1), 16 Del.C. §122(3)(h), and 29 Del.C. §7904 the Department of Health and Social Services, Division of Public Health, State of Delaware adopts the following regulations pertaining to the testing of newborns for various disorders.</p> <p><b>PURPOSE:</b> ...Each newborn delivered in the state must be provided a panel of screening tests to identify certain metabolic, hematologic and endocrinologic disorders that may result in developmental delay, mental retardation, serious medical conditions, or death.</p>	<p><b>4107. 10.0 Religious Exemption From Testing: ...10.2</b> In the event a religious exemption is claimed from the requirements for testing for Hereditary Disorders, the person otherwise responsible for submitting the specimen for testing shall be responsible for submitting a completed affidavit to the Delaware Newborn Screening Program Office, signed by the infant's parent or legal guardian, using the following language:</p> <ol style="list-style-type: none"> <li>1. (I) (We) (am) (are) the (parent(s)) (legal guardian(s)) of (name of child)</li> <li>2. (I) (We) hereby (swear) (affirm) that (I) (we) subscribe to a belief in a relation to a Supreme Being involving duties superior to those arising from any human relation.</li> <li>3. (I) (We) further (swear) (affirm) that our belief is sincere and meaningful and occupies a place in (my) (our) life parallel to that filled by the orthodox belief in God.</li> <li>4. This belief is not a political, sociological or philosophical view of a merely personal moral code.</li> <li>5. This belief causes (me) (us) to request an exemption from the requirements for testing for Hereditary Disorders by the Delaware Newborn Screening Program for _____ (name of child).</li> </ol> <p><b>4107. 10.3</b> The Newborn Screening Refusal Form will be provided through the Newborn Screening Program Office.</p>	<p><b>4107. ...8.0 Confidentiality Of Records ...8.1</b> The Newborn Screening Program shall maintain and treat as confidential all newborn screening communications with institutions, families and health care providers. The Newborn Screening Program shall maintain and treat as confidential a record of every newborn in whom a diagnosis of one or more of the various metabolic, hematologic, or endocrinologic disorders is confirmed.</p> <p><b>8.2</b> Information may be disclosed by the Newborn Screening Program in summary forms, which do not identify individuals. Individuals or institutions requesting summary data must submit a proposal to the Newborn Screening Program and to the Institutional Review Board of the Division of Public Health.</p>	NO	YES-religious

**Vaccination Surveillance System**

State	Statute/Rule	Language Specific to Surveillance System	Exemption	Data Sharing	Consent Required?	Dissent Allowed?
DE	NO STATUTE FOUND  RULE: D.A.C. 4202, 7.1.14	<p><b>7.0 Control of Specific Contagious Diseases.</b></p> <p><b>7.1 Vaccine Preventable Disease.</b></p> <p><b>7.1.14</b> The Division Director may maintain a registry of the immunization status of persons vaccinated against any vaccine preventable diseases (hereafter called an "immunization registry."</p> <p><b>7.1.14.1.</b> Physicians and other health care providers who give immunizations shall report information about the immunization and the person to whom it was given for addition to the immunization registry in a manner prescribed by the Division Director or designee... (9 DE Reg. 1188 (2/1/06))</p>	<p>"The Division of Public Health's (DPH) Communicable Disease Regulations mandate that all immunizations must be reported to the DPH Immunization Registry." – <i>Delaware Dept. of Health, <a href="http://dhss.delaware.gov/dhss/dph/dpc/immunize-providers.html">http://dhss.delaware.gov/dhss/dph/dpc/immunize-providers.html</a></i></p>	<p><b>7.1.14.2</b> The Division Director or designee may disclose information from the immunization registry without a patient's, parent's, or guardian's written release authorizing such disclosure to the following:</p> <p><b>7.1.14.2.1</b> The person immunized, or a parent or legal guardian of the person immunized, or persons delegated in writing by same.</p> <p><b>7.1.14.2.2</b> Employees of public agencies or research institutions, however only when it can be shown that the intended use of the information is consistent with the purposes of this section.</p> <p><b>7.1.14.2.3</b> Health records staff of school districts and child care facilities.</p> <p><b>7.1.14.2.4</b> Persons who are other than public employees who are entrusted with the regular care of those under the care and custody of a state agency including but not limited to operators of day care facilities, group, residential care facilities and adoptive or foster parents.</p> <p><b>7.1.14.2.5</b> Health insurers, however only when the person immunized is a client of the health insurer.</p> <p><b>7.1.14.2.6</b> Health care professionals or their authorized employees who have been given responsibility for the care of the person immunized.</p> <p><b>7.1.14.3</b> If any person authorized in subsection 6.1.14.2 discloses information from the immunization registry for any other purpose, it is an unauthorized release and such person may be subject to civil and criminal penalty.</p>	NO	NO