

# VIRGINIA

## Birth Defects Surveillance System

State	Statute/Rule	Language Specific to Surveillance System	Data Sharing	Research Authority	Consent Required?	Dissent Allowed?
VA	<p>STATUTE: Code of Virginia, Title 32.1 Chapter 2</p> <p>RULE: Virginia Administrative Code, Title 12, Agency 5, Chapter 191,</p>	<p><b>§ 32.1-69.1. Virginia Congenital Anomalies Reporting and Education System. A.</b> In order to collect data to evaluate the possible causes of birth defects, improve the diagnosis and treatment of birth defects and establish a mechanism for informing the parents of children identified as having birth defects and their physicians about the health resources available to aid such children, the Commissioner shall establish and maintain a Virginia Congenital Anomalies Reporting and Education System using data from birth and death certificates and fetal death reports filed with the State Registrar of Vital Records and data obtained from hospital medical records. The chief administrative officer of every hospital, as defined in § 32.1-123, shall make or cause to be made a report to the Commissioner of any person under two years of age diagnosed as having a congenital anomaly. The Commissioner may appoint an advisory committee to assist in the design and implementation of this reporting and education system with representation from relevant groups including, but not limited to, physicians, geneticists, personnel of appropriate state agencies, persons with disabilities and the parents of children with disabilities.</p> <p><b>B.</b> The Commissioner shall provide for a secure system, which may include online data entry that protects the confidentiality of data and information for which reporting is required, to implement the Virginia Congenital Anomalies Reporting and Education System. At a minimum, data collected shall include, but need not be limited to, the following: <b>(i)</b> the infant's first and last name, date of birth, gender, state of residence, birth hospital, physician's name, date of admission, date of discharge or transfer, and diagnosis; <b>(ii)</b> the first and last names of the infant's mother and father; <b>(iii)</b> the first and last name of the primary contact person for the infant; and <b>(iv)</b> data pertaining to birth defects reported by hospitals and derived from birth and death certificates and fetal death reports filed with the State Registrar of Vital Records and such other sources as may be authorized by the Commissioner.</p>	<p><b>§ 32.1-69.2. Confidentiality of records; publication; authority of Commissioner to contact parents and physicians.</b> The Commissioner and all other persons to whom data is submitted pursuant to § 32.1-69.1 shall keep such information confidential. For the purpose of only complying with the provisions of § 32.1-69.1, hospitals required to report birth defects to the Virginia Congenital Anomalies Reporting and Education System and provide patient follow-up may view personally identifiable information in the system as approved by the Commissioner and upon receipt by the Commissioner of sworn affirmation from each such person that the confidentiality of the information will be preserved. No publication of information shall be made except in the form of statistical or other studies which do not identify individuals. However, the Commissioner may contact the parents of children identified as having birth</p>	<p><b>§ 32.1-69.2.</b> ...No publication of information shall be made except in the form of statistical or other studies which do not identify individuals. However, the Commissioner may contact the parents of children identified as having birth defects and their physicians to collect relevant data and to provide them with information about available public and private health care resources.</p> <p><b>2VAC5-191-280. Scope and content of the Virginia Congenital Anomalies Reporting and Education System</b></p> <p>...<b>D. Goals. 1.</b> Children with birth defects will receive early diagnosis and assistance in finding and accessing health care services.</p>	NO	NO

		<p>The Commissioner, as he deems necessary to facilitate the follow-up of infants whose data and health record information have been entered into the system, <b>may authorize the integration or linking of the Virginia Congenital Anomalies Reporting and Education System with other Department of Health population-based surveillance systems.</b></p> <p>In addition, to minimize duplication and ensure accuracy during data entry, the Commissioner may authorize hospitals required to report birth defect data to the system to view such existing data and information as may be designated by the Commissioner.</p>	<p>defects and their physicians to collect relevant data and to provide them with information about available public and private health care resources.</p>	<p><b>2.</b> Birth defect surveillance data will be used in making decisions regarding health services planning and to promote scientific collaboration for the prevention of birth defects.</p>		
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**Cancer Surveillance System**

State	Statute/Rule	Language Specific to Surveillance System	Data Sharing	Research Authority	Consent Required?
VA	<p>STATUTE: CV, Title 32.1, Article 9, Chapter 2</p> <p>RULE: V.A.C., Title 12, Agency 5, Chapter 90, Section 150, Part VIII</p>	<p><b>§ 32.1-70. Information from hospitals, clinics, certain laboratories and physicians supplied to Commissioner; statewide cancer registry.</b> A. Each hospital, clinic and independent pathology laboratory shall make available to the Commissioner or his agents information on patients having malignant tumors or cancers. A physician shall report information on patients having cancers unless he has determined that a hospital, clinic or in-state pathology laboratory has reported the information. This reporting requirement shall not apply to basal and squamous cell carcinoma of the skin. Such information shall include the name, address, sex, race, diagnosis and any other pertinent identifying information regarding each such patient and shall include information regarding possible exposure to Agent Orange or other defoliants through their development, testing or use or through service in the Vietnam War. Each hospital, clinic, independent pathology laboratory, or physician shall provide other available clinical information as defined by the Board of Health.</p> <p><b>B.</b> From such information the Commissioner shall establish and maintain a statewide cancer registry. The purpose of the statewide cancer registry shall include but not be limited to: <b>1.</b> Determining means of improving the diagnosis and treatment of cancer patients. <b>2.</b> Determining the need for and means of providing better long-term, follow-up care of cancer patients. <b>2a.</b> Conducting epidemiological analyses of the incidence, prevalence, survival, and risk factors associated with the occurrence of cancer in Virginia. <b>3.</b> Collecting data to evaluate the possible carcinogenic effects of environmental hazards including exposure to dioxin and the defoliant, Agent Orange. <b>4.</b> Improving rehabilitative programs for cancer patients. <b>5.</b> Assisting in the training of hospital personnel. <b>6.</b> Determining other needs of cancer patients and health personnel.</p>	<p><b>§ 32.1-70.2. Collection of cancer case information by the Commissioner.</b> A. Using such funds as may be appropriated therefor, the Commissioner or his designee may perform on-site data collection of the records of patients having malignant tumors or cancers at those consenting hospitals, clinics, independent pathology laboratories and physician offices required to report information of such patients pursuant to the reporting requirements of § 32.1-70, in order to ensure the completeness and accuracy of the statewide cancer registry.</p> <p><b>B.</b> The selection criteria for determining which consenting hospitals, clinics, independent pathology laboratories and physician offices may be subject to on-site data collection under the provisions of this section shall include, but shall not be limited to: <b>(i)</b> expected annual number of cancer case reports, <b>(ii)</b> historical completeness and accuracy of reporting rates, and <b>(iii)</b> whether the facility maintains its own cancer registry.</p> <p><b>C.</b> The Board of Health shall promulgate regulations necessary to implement the provisions of this section.</p>	<p><b>§ 32.1-71. Confidential nature of information supplied; publication; reciprocal data-sharing agreements.</b> A. The Commissioner and all persons to whom information is submitted in accordance with § 32.1-70 shall keep such information confidential. Except as authorized by the Commissioner in accordance with the provisions of § 32.1-41, no release of any such information shall be made except in the form of statistical or other studies which do not identify individual cases.</p> <p><b>B.</b> The Commissioner may enter into reciprocal data-sharing agreements with other cancer registries for the exchange of information. Upon the provision of satisfactory assurances for the preservation of the confidentiality of such information, patient-identifying information may be exchanged with other cancer registries which have entered into reciprocal data-sharing agreements with the Commissioner.</p> <p><b>§ 32.1-41. Anonymity of patients and practitioners to be preserved in use of medical records.</b> The Commissioner or his designee shall preserve the anonymity of each patient and practitioner of the healing arts whose records are examined pursuant to § 32.1-40 except that the Commissioner, in his sole discretion, may divulge the identity of such patients and practitioners if pertinent to an investigation, research or study. Any person to whom such identities are divulged shall preserve their anonymity.</p>	NO

		<p><b>12VAC5-90-180. Report contents and procedures.</b> ...Reports shall be made within six months of the diagnosis of cancer and submitted to the Virginia Cancer Registry on a monthly basis. Cancer programs conducting annual follow-up on patients shall submit follow-up data monthly in an electronic format approved by the Virginia Cancer Registry.</p> <p><b>12VAC5-90-180. Report contents and procedures.</b> Each report shall include the patient's name, address (including county or independent city of residence), age, date of birth, sex, date of diagnosis, date of admission or first contact, primary site of cancer, histology (including type, behavior, and grade), basis of diagnosis, social security number, race, ethnicity, marital status, usual occupation, usual industry, sequence number, laterality, stage, treatment, recurrence information (when applicable), name of reporting facility, vital status, cause of death (when applicable), date of last contact, history of tobacco and alcohol use, and history of service in Vietnam and exposure to dioxin-containing compounds, when applicable.</p>	<p><b>32.1-71.02. Notification of cancer patients of statewide cancer registry reporting.</b> A. Any physician diagnosing a malignant tumor or cancer shall, at such time and in such manner as considered appropriate by such physician, notify each patient whose name and record abstract is required to be reported to the statewide cancer registry pursuant to § <a href="#">32.1-70</a> that personal identifying information about him has been included in the registry as required by law. Any physician required to so notify a patient that personal identifying information about him has been included in the cancer registry may, when, in the opinion of the physician, such notice would be injurious to the patient's health or well-being, provide the required notice to the patient's authorized representative or next of kin in lieu of notifying the patient.</p> <p><i>B. Upon request to the statewide cancer registry, the patient whose personal identifying information has been submitted to such registry shall have a right to know the identity of the reporter of his information to such registry.</i> <i>[emphasis added]</i></p> <p><b>2VAC5-90-170. Those required to report.</b> ...Any person making such report shall be immune from liability as provided by §<a href="#">32.1-38</a> of the Code of Virginia.</p>	<p><b>§ 32.1-40. Authority of Commissioner to examine medical records.</b> Every practitioner of the healing arts and every person in charge of any medical care facility shall permit the Commissioner or his designee to examine and review any medical records which he has in his possession or to which he has access upon request of the Commissioner or his designee in the course of investigation, research or studies of diseases or deaths of public health importance. No such practitioner or person shall be liable in any action at law for permitting such examination and review.</p>	
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**Newborn Genetic Testing & Surveillance System**

State	Statute/Rule	Language Specific to Genetic Testing and Surveillance System	Exemption	Research Authority	Consent Required?	Dissent Allowed?
VA	<p>STATUTE: C.V., Title 32.1, Chapter 2</p> <p>RULE: V.A.C., Title 12, Agency 5, Chapters 71 and 191</p>	<p><b>§ 32.1-65. Certain newborn screening required.</b> In order to prevent mental retardation and permanent disability or death, every infant who is born in the Commonwealth shall be subjected to screening tests for various disorders consistent with, but not necessarily identical to, the uniform condition panel recommended by the American College of Medical Genetics in its report, Newborn Screening: Toward a Uniform Screening Panel and System, that was produced for the U.S. Department of Health and Human Services. Further, upon the issuance of guidance for states' newborn screening programs by the federal Department of Health and Human Services, every infant who is born in the Commonwealth shall be screened for a panel of disorders consistent with, but not necessarily identical to, the federal guidance document.</p> <p><b>§ 32.1-66. Commissioner to notify physicians; reports to Commissioner.</b> Whenever a newborn screening test result indicates suspicion of any condition pursuant to § <a href="#">32.1-65</a>, the Commissioner shall notify forthwith the attending physician and shall perform or provide for additional testing required to confirm or disprove the diagnosis. All physicians, certified nurse midwives, public health nurses, or any nurse receiving such test result, and administrators of hospitals in the Commonwealth, shall report the discovery of all cases of any condition for which newborn screening is conducted pursuant to § <a href="#">32.1-65</a> to the Commissioner for infants and children <b>up to two years of age</b>. <i>[emphasis added]</i></p> <p><b>12VAC5-71-10. Definitions.</b> The following words and terms when used in this regulation shall have the following meanings unless the context clearly indicates otherwise:</p> <p>"Dried-blood-spot specimen" means a clinical blood sample collected from an infant by heel stick method and placed directly onto specially manufactured absorbent specimen collection (filter) paper.</p>	<p><b>§ 32.1-65.</b> ...Any infant whose parent or guardian objects thereto on the grounds that such tests conflict with his religious practices or tenets shall not be required to receive such screening tests.</p> <p><b>12VAC5-71-40. Religious exemption from newborn dried-blood-spot screening requirements.</b> Refusal by the infant's parent or guardian to consent to the collection and submission of a newborn dried-blood-spot screening specimen because the test conflicts with his religious practices or tenets shall be documented in the medical record and communicated to the department.</p> <p><b>12VAC5-71-50. Responsibilities of the physician or midwife.</b> For every live birth in the Commonwealth, the physician or midwife in charge of the infant's care after delivery shall cause the initial collection and submission of a newborn dried-blood-spot screening specimen for testing of those heritable disorders and genetic diseases listed in 12VAC5-71-30 D and <b>in accordance with 12VAC5-71-70 or 12VAC5-71-80</b>. <i>[emphasis added; NOTE: no mention of being in accordance with the 12VAC5-71-40 exemption]</i></p> <p><b>12VAC5-71-90. Responsibilities of the chief executive officer.</b> The chief executive officer shall assure that the hospital providing birthing services develops and implements policies and procedures to make certain that the following steps take place:</p>	<p><b>§ 32.1-67.1. Confidentiality of records; prohibition of discrimination.</b> The results of the newborn screening services conducted pursuant to this article may be used for research and collective statistical purposes. No publication of information, biomedical research, or medical data shall be made that identifies any infant having a heritable or genetic disorder. All medical records maintained as part of newborn screening services shall be confidential and shall be accessible only to the Board, the Commissioner, or his agents.</p> <p><b>§32.1-69. Records confidential; disclosure of results of screening.</b> The results of any particular screening program shall be sent to the physician of the person tested, if known, and either to the parents when the person screened is under the age of eighteen or to the person if he is eighteen years of age or over. The results of a screening program may be used for research and collective statistical purposes. Except as hereinabove provided, all records maintained as part of any screening program shall be strictly confidential and shall be accessible only to the Board, the Commissioner or his agents or to the local health director who is conducting the screening program except by explicit permission of</p>	NO	YES

		<p>"Heritable disorders and genetic diseases" means pathological conditions (i.e., interruption, cessation or disorder of body functions, systems, or organs) that are caused by an absent or defective gene or gene product, or by a chromosomal aberration.</p> <p>"Infant" means a child less than 12 months of age.</p> <p>"Population-based" means preventive interventions and personal health services developed and available for the entire infant and child health population of the Commonwealth rather than for individuals in a one-on-one situation.</p> <p>"Virginia Newborn Screening System" means a coordinated and comprehensive group of services, including education, screening, follow up, diagnosis, treatment and management, and program evaluation, managed by the department's Virginia Newborn Screening Services and Virginia Early Hearing Detection and Intervention Program for safeguarding the health of children born in Virginia.</p> <p><b>12VAC5-71-30. Core panel of heritable disorders and genetic diseases. ...D.</b> Infants under six months of age who are born in Virginia shall be screened in accordance with the provisions set forth in this chapter for the following heritable disorders and genetic diseases, which are identified through newborn dried-blood-spot screening tests:...</p> <p><b>12VAC5-71-100. Responsibilities of the testing laboratory providing newborn dried-blood-spot screening tests.</b></p> <p>A. Newborn dried-blood-spot screening tests shall be performed by the Division of Consolidated Laboratory Services or other laboratory the department has contracted with to provide this service in accordance §32.1-65 of the Code of Virginia.</p>	<ol style="list-style-type: none"> <li>1. Collection of newborn dried-blood-spot screening specimens shall occur after 24 hours of birth, and collection and submission of the specimens shall meet the standards required by the testing laboratory;</li> <li>2. Notification of the newborn's physician of record or designee shall occur within one business day in the event that the infant is discharged before the newborn dried-blood-spot screening specimen has been collected;</li> <li>3. Communication of the newborn dried-blood-spot screening test results to the newborn's physician of record or designee shall occur so that test results may become part of the infant's medical record on file with the physician;</li> <li>4. Information relative to newborn screening dried-blood-spot results and treatment shall be recorded in the patient's medical record, and retention of the information shall comply with applicable medical record retention requirements; and</li> <li>5. Training of staff on newborn dried-blood-spot screening specimen collection and submission and parental notification shall be implemented in a way that ensures an adequately trained and knowledgeable workforce is maintained for implementing specimen collection and submission and parental notification according to standards required by the testing laboratory and guidance from the department. <i>[NOTE: nothing about option to refuse]</i></li> </ol>	<p>the person who has been screened if such person is eighteen years of age or over or of such person's parent or guardian if he is under age eighteen.</p>		
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Vaccination Surveillance System

State	Statute/Rule	Language Specific to Surveillance System	Exemption	Data Sharing	Consent Required?	Dissent Allowed?
VA	STATUTE: C.V., Title 32.1 Chapter 2  12VAC5- 115 (Chapter 115)	<i>DOH Website lists two laws as authority. No rule.</i> <b>§ 32.1-46.01. Virginia Immunization Information System.</b> A. The Board of Health shall establish the Virginia Immunization Information System (VIIS), a statewide immunization registry that <i>consolidates patient immunization histories from birth to death</i> into a complete, accurate, and definitive record that may be made available to participating health care providers throughout Virginia, to the extent funds are appropriated by the General Assembly or otherwise made available. The purposes of VIIS shall be to (i) protect the public health of all citizens of the Commonwealth, (ii) prevent under- and over-immunization of children, (iii) ensure up-to-date recommendations for immunization scheduling to health care providers and the Board, (iv) generate parental reminder and recall notices and manufacturer recalls, (v) develop immunization coverage reports, (vi) identify areas of under-immunized population, and (vii) provide, in the event of a public health emergency, a mechanism for tracking the distribution and administration of immunizations, immune globulins, or other preventive medications or emergency treatments. <i>[emphasis added]</i>	<i>Proposed Rule (accessed 8/18/12)</i> <b><u>12VAC5-115-50. Registration procedures.</u></b>  A. <u>Participation in VIIS is voluntary.</u>  B. <u>Completed registration forms from authorized participants must be processed and approved by VDH before access to the system is allowed. Registration will require the participant to assure compliance with necessary confidentiality and security access provisions that specify security procedures to ensure that VIIS data are protected from unauthorized view and access. The participant shall update and submit the forms to VDH every year.</u>  C. <u>Once the participant is approved, VDH will provide training and activate the participant in the VIIS system.</u>  <b><u>12VAC5-115-60. Patient confidentiality.</u></b>  <u>...C. Patients shall have the opportunity to opt-out of VIIS by doing one of the following:</u>	<b>§ 32.1-46.01. Virginia Immunization Information System. ...B.</b> The Board of Health shall promulgate regulations to implement the VIIS that shall address:  1. Registration of voluntary participants, including, but not limited to, a list of those health care entities that are authorized to participate and any forms and agreements necessary for compliance with the regulations concerning <i>patient privacy promulgated by the federal Department of Health and Human Services;...[emphasis added]</i>  ...6. The patient identifying data to be reported, including, but not limited to, the patient's name, date of birth, gender, telephone number, home address, birth place, and mother's maiden name;  7. The patient immunization information to be reported, including, but not necessarily limited to, the type of immunization administered (specified by current procedural terminology (CPT) code or Health Level 7 (HL7) code); date of administration; identity of administering person; lot number; and if present, any contraindications, or religious or medical exemptions;  8. Mechanisms for entering into data-sharing agreements with other state and regional immunization registries for the exchange, on a periodic nonemergency basis and in the event of a public health emergency, of patient immunization information, after receiving, in writing, satisfactory assurances for the preservation of confidentiality, a clear description of the data requested, specific details on the intended use of the data, and the identities of the persons with whom the data will be shared;  9. Procedures for the use of vital statistics data, including, but not necessarily limited to, the linking of birth certificates and death certificates;	NO	NO

		<p><b>C.</b> The establishment and implementation of VIIS is hereby declared to be a necessary public health activity to ensure the integrity of the health care system in Virginia and to prevent serious harm and serious threats to the health and safety of individuals and the public. Pursuant to the regulations concerning patient privacy promulgated by the federal Department of Health and Human Services, covered entities may disclose protected health information to the secure system established for VIIS without obtaining consent or authorization for such disclosure. Such protected health information shall be used exclusively for the purposes established in this section.</p> <p><b>D.</b> The Board and Commissioner of Health, any employees of the health department, any voluntary participant, and any person authorized to report or disclose immunization data hereunder shall be immune from civil liability in connection therewith unless such person acted with gross negligence or malicious intent...</p>		<p><b>10.</b> Procedures for requesting immunization records that are in compliance with the requirements for disclosing health records set forth in § <a href="#">32.1-127.1:03</a>; such procedures shall address the approved uses for the requested data, to whom the data may be disclosed, and information on the provisions for disclosure of health records pursuant to § <a href="#">32.1-127.1:03</a>;</p> <p><b>11.</b> Procedures for releasing aggregate data, from which personal identifying data has been removed or redacted, to qualified persons for purposes of research, statistical analysis, and reporting; and</p> <p><b>12.</b> Procedures for the Commissioner of Health to access and release, as necessary, the data contained in VIIS in the event of an epidemic or an outbreak of any vaccine-preventable disease or the potential epidemic or epidemic of any disease of public health importance, public health significance, or public health threat for which a treatment or vaccine exists...</p> <p><b>§32.1-46 Immunization of patients against certain diseases.</b> ...E. For the purpose of protecting the public health by ensuring that each child receives age-appropriate immunizations, any physician, physician assistant, nurse practitioner, licensed institutional health care provider, local or district health department, the Virginia Immunization Information System, and the Department of Health may share immunization and patient locator information without parental authorization, including, but not limited to, the month, day, and year of each administered immunization; the patient's name, address, telephone number, birth date, and social security number; and the parents' names. The immunization information; the patient's name, address, telephone number, birth date, and social security number; and the parents' names shall be confidential and shall only be shared for the purposes set out in this subsection.</p>		
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