

Virginia

Newborn Genetic Testing & Surveillance System

State	Statute/Rule	Language Specific to Genetic Testing and Surveillance System	Exemption	Research Authority	Consent Required?	Dissent Allowed?
VA	STATUTE: C.V., Title 32.1, Chapter 2 RULE: V.A.C., Title 12, Agency 5, Chapters 71 and 191	§ 32.1-65. Certain newborn screening required. 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	§ 32.1-65. ... 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.	§ 32.1-67.1. Confidentiality of records; prohibition of discrimination. 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	NO	YES

		<p>disorders consistent with, but not necessarily identical to, the federal guidance document.</p> <p>§ 32.1-66. Commissioner to notify physicians; reports to Commissioner. Whenever a newborn screening test result indicates suspicion of any condition pursuant to § 32.1-65, 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 § 32.1-65 to the Commissioner for infants and children up to two years of age. <i>[emphasis added]</i></p>	<p>12VAC5-71-40. Religious exemption from newborn dried-blood-spot screening requirements. 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>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>		
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		<p>12VAC5-71-10. Definitions. 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>"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</p>	<p>12VAC5-71-50. Responsibilities of the physician or midwife. 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 <i>in accordance with 12VAC5-71-70 or 12VAC5-71-80.</i> [emphasis added; NOTE: no mention of being in accordance with the 12VAC5-71-40 exemption]</p>	<p>§32.1-69. Records confidential; disclosure of results of screening. 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</p>		
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		<p>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>12VAC5-71-30. Core panel of heritable disorders and genetic diseases. ...D. 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>12VAC5-71-90. Responsibilities of the chief executive officer. 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>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;</p>	<p>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 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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		<p>12VAC5-71-100. Responsibilities of the testing laboratory providing newborn dried-blood-spot screening tests.</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> <p>B. The testing laboratory shall maintain accreditation under the Clinical Laboratory Improvement Amendments as defined in 42 CFR Part 493. ...</p> <p>...E. The testing laboratory shall provide the department's newborn screening services with the newborn dried-blood-spot screening test data that are necessary to carry out follow-up services. ...</p>	<p>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;</p> <p>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;</p>			
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		<p>...H. The testing laboratory shall maintain an information management system capable of electronic data exchange between the laboratory and the department's newborn screening services.</p>	<p>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</p> <p>5. Training of staff on</p>			
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			<p>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. [NOTE: nothing about option to refuse]</p>			
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