

TITLE 12. HEALTH

STATE BOARD OF HEALTH

Emergency Regulation

Titles of Regulations: **12VAC5-71. Regulations Governing Virginia Newborn Screening Services (amending 12VAC5-71-30, 12VAC5-71-150; adding 12VAC5-71-200 through 12VAC5-71-260).**

12VAC5-191. State Plan for the Children with Special Health Care Needs Program (amending 12VAC5-191-260).

Statutory Authority: §§ 32.1-12, 32.1-65.1, and 32.1-67 of the Code of Virginia.

Effective Dates: December 24, 2014, through June 23, 2016.

Agency Contact: Dev Nair, Director, Division of Policy and Evaluation, Department of Health, 109 Governor Street, Richmond, VA 23219, telephone (804) 864-7662, FAX (804) 864-7647, or email dev.nair@vdh.virginia.gov.

Preamble:

Congenital heart defects are the most common birth defects in the United States, affecting about one in every 110 babies. A few babies born with congenital heart defects have more serious forms of heart disease, critical congenital heart disease (CCHD). CCHDs are heart defects that result in abnormal blood flow and oxygen deprivation. These defects require intervention within the first year of life and delayed diagnosis can result in death. Screening newborns for CCHD using pulse oximetry has been recommended through the U.S. Department of Health and Human Services Secretary's Recommended Uniform Screening Panel. The screening is simple, quick, and painless. A sensor wrapped around the baby's right hand or either foot measures the amount of oxygen in the baby's blood.

Most Virginia hospitals already provide CCHD screening voluntarily. These regulations would require a small number of additional hospitals to implement the screening. The regulations will also permit the Virginia Department of Health (VDH) to collect information via the Virginia Congenital Anomalies Reporting and Education System (VaCARES) reporting system so that infants identified with a critical congenital heart disease could be referred to the Care Connections for Children program in order to obtain care coordination services.

Chapters 4 and 175 of the 2014 Acts of Assembly require VDH to implement regulations relating to screening for CCHD. The legislation requires VDH to promulgate these regulations within 280 days of enactment. Pursuant to the legislation, the regulations include provisions to implement CCHD screening for all babies born in hospitals with newborn nurseries. The legislation also requires VDH to convene a workgroup to provide information and recommendations for the development of the regulations.

12VAC5-71-30. Core panel of heritable disorders and genetic diseases.

A. The Virginia Newborn Screening System, which includes the Virginia Newborn Screening Program and the Virginia Early Hearing Detection and Intervention Program, and Virginia critical congenital heart disease screening, shall ensure that the core panel of heritable disorders and genetic diseases for which newborn screening is conducted is consistent with but not

necessarily identical to the U.S. Department of Health and Human Services Secretary's Recommended Uniform Screening Panel.

B. The department shall review, at least biennially, national recommendations and guidelines and may propose changes to the core panel of heritable disorders and genetic diseases for which newborn dried-blood-spot screening tests are conducted.

C. The Virginia Genetics Advisory Committee may be consulted and provide advice to the commissioner on proposed changes to the core panel of heritable disorders and genetic diseases for which newborn dried-blood-spot screening tests are conducted.

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:

1. Argininosuccinic aciduria (ASA);
2. Beta-Ketothiolase deficiency (BKT);
3. Biotinidase deficiency (BIOT);
4. Carnitine uptake defect (CUD);
5. Classical galactosemia (galactose-1-phosphate uridylyltransferase deficiency) (GALT);
6. Citrullinemia type I (CIT-I);
7. Congenital adrenal hyperplasia (CAH);
8. Cystic fibrosis (CF);
9. Glutaric acidemia type I (GA I);
10. Hb S beta-thalassemia (Hb F,S,A);
11. Hb SC-disease (Hb F,S,C);
12. Hb SS-disease (sickle cell anemia) (Hb F, S);
13. Homocystinuria (HCY);
14. Isovaleric acidemia (IVA);
15. Long chain L-3-Hydroxy acyl-CoA dehydrogenase deficiency (LCHAD);
16. Maple syrup urine disease (MSUD);
17. Medium-chain acyl-CoA dehydrogenase deficiency (MCAD);
18. Methylmalonic acidemia (Methylmalonyl-CoA mutase deficiency) (MUT);
19. Methylmalonic acidemia (Adenosylcobalamin synthesis deficiency) (CBL A, CBL B);
20. Multiple carboxylase deficiency (MCD);
21. Phenylketonuria (PKU);
22. Primary congenital hypothyroidism (CH);
23. Propionic acidemia (PROP);
24. Tyrosinemia type I (TYR I);
25. Trifunctional protein deficiency (TFP);
26. Very long-chain acyl-CoA dehydrogenase deficiency (VLCAD);
27. 3-hydroxy 3-methyl glutaric aciduria (HMG); and
28. 3-Methylcrotonyl-CoA carboxylase deficiency (3-MCC).

E. Infants born in Virginia shall be screened for hearing loss in accordance with provisions set forth in §§ 32.1-64.1 and 32.1-64.2 of the Code of Virginia and as governed by 12VAC5-80.

F. Newborns born in Virginia shall be screened for critical congenital heart disease in accordance with provisions set forth in §§ 32.1-65.1 and 32.1-67 of the Code of Virginia and as governed by 12VAC5-71-200 through 12VAC5-71-260.

12VAC5-71-150. Responsibilities of the Care Connection for Children network.

A. The Care Connection for Children network shall provide the following services:

1. Care coordination services for residents of the Commonwealth who are diagnosed with selected heritable disorders ~~or~~, genetic diseases, or critical congenital heart disease and are referred to the network by the Virginia Newborn Screening Program.
2. Other network services for eligible individuals in accordance with ~~the~~ § 32.1-77 of the Code of Virginia and applicable regulations.

B. The Care Connection for Children network shall provide data as needed by the department's newborn screening program.

12VAC5-71-200. Definitions related to critical congenital heart disease screening.

As used in the following sections relating to critical congenital heart disease screening, the following words and terms shall have the following meanings unless the context clearly indicates otherwise:

"Abnormal screening results" means all results that indicate the newborn has not passed the screening test.

"Critical congenital heart disease" or "CCHD" means a congenital heart disease that places a newborn at significant risk of disability or death if not diagnosed and treated soon after birth. The disease may include, but is not limited to hypoplastic left heart syndrome, pulmonary atresia (with intact septum), tetralogy of fallot, total anomalous pulmonary venous return, transposition of the great arteries, tricuspid atresia, and truncus arteriosus.

"CCHD screening" means the application of screening technology to detect CCHD.

"Echocardiogram" means a test that uses an ultrasound to provide an image of the heart.

"Licensed practitioner" means a licensed health care provider who is permitted, within the scope of his practice pursuant to Chapter 29 (§ 54.1-2900 et seq.) or Chapter 30 (§ 54.1-3000 et seq.) of Title 54.1 of the Code of Virginia to provide care to a newborn.

"Newborn" means a person in the first 28 days of life who was born in Virginia or on federal property within Virginia.

"Newborn nursery" means a general level, intermediate level, or specialty level newborn service as defined in 12VAC5-410-443 B 1, 2, and 3.

"Screening technology" means pulse oximetry testing in the right hand and either foot. Screening technology shall also include alternate medically accepted tests that measure the percentage of blood oxygen saturation, follow medical guideline consensus and recommendations issued by the American Academy of Pediatrics, and are approved by the Board of Health.

"Specialty nursery" means the same as defined in 12VAC5-410-443 B 3 and as further defined as Level III Neonatal Care by the Guidelines for Perinatal Care (7th edition) written by the American Academy of Pediatrics and the American College of Obstetrics and Gynecology.

"Subspecialty nursery" means the same as defined in 12VAC5-410-443 B 4.

12VAC5-71-210. Critical congenital heart disease screening protocols.

A. Hospitals shall develop protocols for critical congenital heart disease screening in accordance with 12VAC5-71-200 through 12VAC5-72-260 and national recommendations from the American Academy of Pediatrics.

B. Hospitals shall develop protocols for the physical evaluation by licensed practitioners of newborns with abnormal screening results.

C. Hospitals shall develop protocols for the referral of newborns with abnormal screening results, if needed, after evaluation.

12VAC5-71-220. Critical congenital heart disease screening.

A. A licensed practitioner shall perform the screening.

B. Except as specified in subsection C of this section and 12VAC5-71-260, CCHD screening shall be performed on every newborn in the birth hospital between 24 and 48 hours of life or, if the newborn is discharged from the hospital before reaching 24 hours of life, the CCHD screening shall be performed as late as practical before discharge.

C. If CCHD screening is not indicated, the reason shall be documented in the newborn's medical record. The reasons include but are not limited to:

1. The newborn's current clinical evaluation has included an echocardiogram that ruled out CCHD;
2. The newborn has confirmed CCHD; or
3. The newborn was premature and is still under the care of a specialty or subspecialty nursery.

D. Hospitals shall develop protocols for screening newborns in specialty and subspecialty nurseries in accordance with national recommendations from the American Academy of Pediatrics.

12VAC5-71-230. Critical congenital heart disease screening results.

A. Recording results.

1. All CCHD screening results shall be recorded in the newborn's medical record.
2. All CCHD screening results shall be entered into the electronic birth certificate system with the following information:
 - a. CCHD screening completed; and
 - b. CCHD pass or fail.

B. Abnormal screening results.

1. Abnormal screening results shall be reported by the authorized health care provider who conducted the screening to the attending physician or his designee as soon as the result is obtained.
2. A newborn shall be evaluated by an attending physician or his designee according to the timeframes within the hospital protocol developed in accordance with 12VAC5-71-210 B to complete the protocol recommended by the American Academy of Pediatrics.
3. A newborn shall not be discharged from care until:
 - a. A cause for the abnormal screening result has been determined and a plan is in place for immediate evaluation at another medical facility; or

b. An echocardiogram has been performed and read and an appropriate clinical plan has been developed.

4. Any diagnosis arising from abnormal screening results shall be entered into the electronic birth certificate system.

5. The attending physician or his designee shall provide notification of abnormal results and any diagnoses to the newborn's parent or guardian and to the primary care provider in charge of the newborn's care after the newborn leaves the hospital.

12VAC5-71-240. Referral for care coordination.

A. For any person diagnosed under these regulations, the chief administrative officer of every hospital, as defined in § 32.1-123 of the Code of Virginia, shall make or cause to be made a report to the commissioner in accordance with § 32.1-69.1 of the Code of Virginia.

B. Upon receiving the notification described in subsection A of this section, the Newborn Screening Program at the Virginia Department of Health shall refer the newborn's parent or guardian to the Care Connection for Children network for care coordination services.

12VAC5-71-250. Congenital heart disease screening records.

A. The screening of newborns pursuant to this chapter is a population-based public health surveillance program as defined by the Health Insurance Portability and Accountability Act of 1996 (Pub. L. 104-191; 110 Stat. 2033).

B. Upon request, a hospital shall make available to the Virginia Congenital Anomalies Reporting and Education System (VaCARES):

1. Medical records;

2. Records of laboratory tests; and

3. Any other information that VaCARES considers necessary to:

a. Determine final outcomes of abnormal CCHD screening results; or

b. Evaluate CCHD screening activities in the Commonwealth, including performance of follow-up evaluations and diagnostic tests, initiation of treatment when necessary, and surveillance of the accuracy and efficacy of the screening.

C. Information that the Virginia Department of Health receives under this section is confidential and may only be used or disclosed:

1. For research and collective statistical purposes, pursuant to § 32.1-67.1 of the Code of Virginia;

2. For state or federally mandated statistical reports;

3. To ensure that the information received by the Virginia Department of Health is accurate and reliable; or

4. For reporting to the Virginia Congenital Anomalies Reporting and Education System pursuant to § 32.1-69.1 of the Code of Virginia and 12VAC5-191-280. The Newborn Screening Program shall refer the newborn's parent or guardian to the Care Connection for Children network for care coordination services.

D. The hospital administrator shall ensure that CCHD screening is included in the perinatal quality assurance program and provide the results of the quality improvement program to the Virginia Department of Health upon request.

12VAC5-71-260. Parent or guardian refusal for screening.

A. In the instance of parent or guardian refusal of the CCHD screening based on religious practices or tenets, the parent or guardian refusal shall be documented on a refusal form provided by the Virginia Department of Health and made a part of the newborn's medical record.

B. The administrator of the hospital shall ensure that the Newborn Screening Program at the Virginia Department of Health is notified in writing of the parent or guardian refusal within five days of the newborn's birth.

NOTICE: The following forms used in administering the regulation were filed by the agency. The forms are not being published; however, online users of this issue of the Virginia Register of Regulations may click on the name of a form with a hyperlink to access it. The forms are also available from the agency contact or may be viewed at the Office of the Registrar of Regulations, General Assembly Building, 2nd Floor, Richmond, Virginia 23219.

FORMS (12VAC5-71)

[Notification of Parental Refusal of Dried-Blood-Spot and Critical Congenital Heart Disease Screening \(undated\)](#)

12VAC5-191-260. Scope and content of the Virginia Newborn Screening System.

A. The Virginia Newborn Screening System consists of ~~two~~ three components: (i) Virginia Newborn Screening Services ~~and~~, (ii) Virginia Early Hearing Detection and Intervention Program, and (iii) Virginia critical congenital heart disease screening.

B. Virginia Newborn Screening Services.

1. Mission. The Virginia Newborn Screening Services prevents ~~mental-retardation~~ intellectual disability, permanent disability, or death through early identification and treatment of infants who are affected by selected inherited disorders.

2. Scope of services. The Virginia Newborn Screening Services provides a coordinated and comprehensive system of services to assure that all infants receive a screening test after birth for selected inherited metabolic, endocrine, and hematological disorders as defined in Regulations Governing the Newborn Screening and Treatment Program, ~~12VAC5-70~~ 12VAC5-71.

These population-based, direct, and enabling services are provided through:

- a. Biochemical dried bloodspot screening tests.
- b. Follow up of abnormal results.
- c. Diagnosis.
- d. Education to health professionals and families.
- e. Expert consultation on abnormal results, diagnostic testing, and medical and dietary management for health professionals.

Medical and dietary management is provided for the diagnosed cases and includes assistance in accessing specialty medical services and referral to Care Connection for Children.

The screening and management for specified diseases are governed by Regulations Governing the Newborn Screening and Treatment Program, ~~12VAC5-70~~ 12VAC5-71.

3. Criteria to receive Virginia Newborn Screening Services. All infants born in the Commonwealth are eligible for the screening test for selected inherited disorders.

4. Goal. The Title V national performance measures, as required by the federal Government Performance and Results Act (GPRA-Pub. L. 103-62), are used to establish the program goals. The following goal shall change as needed to be consistent with the Title V national performance measures:

All infants will receive appropriate newborn bloodspot screening, follow up testing, and referral to services.

C. Virginia Early Hearing Detection and Intervention Program.

1. Mission. The Virginia Early Hearing Detection and Intervention Program promotes early detection of and intervention for infants with congenital hearing loss to maximize linguistic and communicative competence and literacy development.

2. Scope of services. The Virginia Early Hearing Detection and Intervention Program provides services to assure that all infants receive a hearing screening after birth, that infants needing further testing are referred to appropriate facilities, that families have the information that they need to make decisions for their children, and that infants and young children diagnosed with a hearing loss receive appropriate and timely intervention services. These population-based and enabling services are provided through:

- a. Technical assistance and education to new parents.
- b. Collaboration with physicians and primary care providers.
- c. Technical assistance and education to birthing facilities and those persons performing home births.
- d. Collaboration with audiologists.
- e. Education to health professionals and general public.

Once diagnosed, the infants are referred to early intervention services. The screening and management for hearing loss are governed by the regulation, Virginia Hearing Impairment Identification and Monitoring System, 12VAC5-80.

3. Criteria to receive services from the Virginia Early Hearing Detection and Intervention Program.

- a. All infants born in the Commonwealth are eligible for the hearing screening.
- b. All infants who are residents of the Commonwealth and their families are eligible for the Virginia Early Hearing Detection and Intervention Program.

4. Goals. The Title V national performance measures, as required by the federal Government Performance and Results Act (GPRA-Pub. L. 103-62), are used to establish the program goals. The following goals shall change as needed to be consistent with the Title V national performance measures:

All infants will receive screening for hearing loss no later than one month of age, achieve identification of congenital hearing loss by three months of age, and enroll in appropriate intervention by six months of age.

D. Virginia critical congenital heart disease screening.

1. Mission. Virginia critical congenital heart disease screening promotes early detection of and intervention for newborns with critical congenital heart disease to maximize positive health outcomes and help prevent disability and death early in life.

2. Scope of services. Newborns receive a critical congenital heart disease screening 24 to 48 hours after birth in a hospital with a newborn nursery, as defined in §§ 32.1-67 and 32.1-

69.1 of the Code of Virginia and the regulations governing critical congenital heart disease screening (12VAC5-71-200 through 12VAC5-71-260). These population-based, direct, and enabling services are provided through:

a. Critical congenital heart disease screening tests using pulse oximetry or other screening technology as defined in 12VAC5-71-200;

b. Hospital reporting of test results pursuant to § 32.1-69.1 of the Code of Virginia and 12VAC5-191-280; and

c. Follow-up, referral processes, and services, as appropriate, through Care Connection for Children.

3. The screening and management for newborn critical congenital heart disease are governed by the regulations governing critical congenital heart disease screening (12VAC5-71-200 through 12VAC5-71-260).

4. Criteria to receive critical congenital heart disease screening. Except as specified in 12VAC5-71-200 C and 12VAC5-71-260, all newborns born in the Commonwealth in a hospital with a newborn nursery shall receive the screening test for critical congenital heart disease 24 to 48 hours after birth using pulse oximetry or other screening technology.

5. Goal. Except as specified in 12VAC5-71-220 C and 12VAC5-71-260, all newborns born in the Commonwealth in a hospital with a newborn nursery shall receive appropriate critical congenital heart disease screening 24 to 48 hours after birth.