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Final Regulation Agency Background Document

Agency name	Virginia Department of Health
Virginia Administrative Code (VAC) citation(s)	12VAC5-71 and 12VAC5-191
Regulation title(s)	Regulations Governing Virginia Newborn Screening Services and State Plan for the Children with Special Health Care Needs Program
Action title	Amend regulations to add critical congenital heart disease (CCHD) to the Virginia Newborn Screening System so that all infants born in hospitals with a newborn nursery in Virginia are screened for CCHD
Date this document prepared	February 17, 2016

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 17 (2014) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual*.

Brief summary

Please provide a brief summary of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed. Alert the reader to all substantive matters or changes. If applicable, generally describe the existing regulation.

The amendments to the newborn screening regulations add requirements for hospitals with a newborn nursery to screen all infants born in Virginia for critical congenital heart disease (CCHD) within 24-48 hours after birth using pulse-oximetry. These amendments require that hospitals develop protocols for the screening of all newborns for CCHD, and that they have protocols for the follow-up and referral for any infants that have positive screens. Newborns that have an abnormal screen shall not be discharged from the hospital until the cause of the abnormal screen has been evaluated and an appropriate plan for care is in place. Any diagnosis resulting from an abnormal screen shall be entered in the electronic birth certificate, and the attending physician shall notify the parent and the primary care provider of the diagnosis. Infants that are diagnosed with CCHD shall be referred to the Care Connection for Children

program for care coordination services. A parent may refuse to have their child screened on the basis of religious practices or tenets. Such refusal must be documented in writing.

Most hospitals in Virginia are already voluntarily performing this screening. The amendments would require a small number of additional hospitals to implement screening. The amendments will also permit VDH to collect information via the VaCARES reporting system so that infants identified with a critical congenital heart disease can be referred to the Care Connections for Children program to obtain care coordination services.

This regulatory action also includes final amendments to the State Plan for Children with Special Health Care Needs Program (12VAC5-191), so that those regulations remain consistent with 12VAC5-71.

Emergency regulations requiring this screening have been in effect since December 24, 2014, as required by HB387/SB183 enacted by the 2014 General Assembly and signed by the Governor. Those emergency regulations will expire on June 23, 2016. This regulatory action seeks to make those changes permanent.

Acronyms and Definitions

Please define all acronyms used in the Agency Background Document. Also, please define any technical terms that are used in the document that are not also defined in the “Definition” section of the regulations.

CCHD – Critical Congenital Heart Disease
 VaCARES – Virginia Congenital Anomalies Reporting and Education System
 VDH – Virginia Department of Health

Statement of final agency action

Please provide a statement of the final action taken by the agency including: 1) the date the action was taken; 2) the name of the agency taking the action; and 3) the title of the regulation.

The Virginia State Board of Health approved the text of the final amendments for the Regulations Governing Virginia Newborn Screening Services and the State Plan for the Children with Special Health Care Needs Program, 12VAC5-71 and 12VAC5-191 on March 17, 2016.

Legal basis

Please identify the state and/or federal legal authority to promulgate this proposed regulation, including: 1) the most relevant citations to the Code of Virginia or General Assembly chapter number(s), if applicable; and 2) promulgating entity, i.e., agency, board, or person. Your citation should include a specific provision authorizing the promulgating entity to regulate this specific subject or program, as well as a reference to the agency/board/person’s overall regulatory authority.

The State Board of Health is authorized to make, adopt, promulgate and enforce regulations by Section 32.1-12 of the Code of Virginia.

Section 32.1-65.1 states that the Board of Health shall require every hospital in Virginia having a newborn nursery to screen infants for critical congenital heart disease.

Section 32.1-67 requires the Board of Health to promulgate regulations.

HB387/SB183 enacted by the General Assembly required the Board of Health to promulgate emergency regulations for CCHD screening. This regulatory action seeks to make those changes permanent.

Purpose

Please explain the need for the new or amended regulation. Describe the rationale or justification of the proposed regulatory action. Describe the specific reasons the regulation is essential to protect the health, safety or welfare of citizens. Discuss the goals of the proposal and the problems the proposal is intended to solve.

Congenital heart defects are the most common birth defects in the United States, affecting about one in every 110 infants. A few infants born with congenital heart defects have more serious forms of heart disease, which are referred to as critical congenital heart disease (affecting approximately 2 of every 1,000 births). 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 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.

In order to help protect the health, safety, and welfare of Virginians, this regulatory action seeks to ensure that all Virginia hospitals with newborn nurseries implement CCHD screening, and that newborns diagnosed with CCHD are reported to VDH so that they may be linked to care coordination services through the Care Connections for Children program.

Substance

Please briefly identify and explain the new substantive provisions, the substantive changes to existing sections, or both.

The final amendments to the newborn screening regulations require all hospitals with a newborn nursery to screen newborns for CCHD within 24-48 hours of birth. Specifically they add the following elements to the existing regulations:

- Hospitals are required to develop protocols for screening, timely evaluation, and timely referral of newborns with abnormal screening results.
- Requirements that a licensed practitioner perform the screening, and setting forth when the screening is to occur. If screening is not indicated, documentation requirements are set forth for the medical record. Hospitals are required to develop screening protocols for specialty and sub-specialty nurseries.
- Requirements that all screening results must be entered into the medical record and the electronic birth certificate system. This section also requires health care providers to report abnormal screening results immediately and to evaluate the newborn in a timely manner. Newborns shall not be discharged unless a cause for the abnormal screening result has been determined or CCHD has been ruled out. Parents or guardians and the infant's primary care provider after discharge from the hospital shall be notified of any abnormal results and any diagnoses.

- Hospitals must report individuals diagnosed with CCHD to VDH so that the newborn's parent or guardian may be referred to care coordination services through the Care Connection for Children program.
- A section specifying what documents shall be provided when requested by the VaCARES system at VDH, and specifying the confidentiality rules for these documents.
- A section that permits parents to refuse CCHD screening based upon religious practices or tenets, and to specify that the hospital must report the refusal to VDH.

Issues

Please identify the issues associated with the proposed regulatory action, including: 1) the primary advantages and disadvantages to the public, such as individual private citizens or businesses, of implementing the new or amended provisions; 2) the primary advantages and disadvantages to the agency or the Commonwealth; and 3) other pertinent matters of interest to the regulated community, government officials, and the public. If there are no disadvantages to the public or the Commonwealth, please indicate.

These amendments will permanently add CCHD screening requirements to the regulations for newborn screening. The primary advantage to VDH, the public, and the Commonwealth is that the regulations will ensure that every infant born in a hospital with a newborn nursery will be screened for CCHD and that those who screen positive will have further evaluation and follow-up as needed. The majority of hospitals that would be affected by these regulations already provide screening for CCHD voluntarily. These amendments to the regulations set minimum standards for this screening. There are no disadvantages to the public or the Commonwealth.

Requirements more restrictive than federal

Please identify and describe any requirement of the proposal which is more restrictive than applicable federal requirements. Include a rationale for the need for the more restrictive requirements. If there are no applicable federal requirements or no requirements that exceed applicable federal requirements, include a statement to that effect.

There are no applicable federal requirements.

Localities particularly affected

Please identify any locality particularly affected by the proposed regulation. Locality particularly affected means any locality which bears any identified disproportionate material impact which would not be experienced by other localities.

There are no known localities that would be specifically impacted by these regulations.

Family impact

Please assess the impact of this regulatory action on the institution of the family and family stability including to what extent the regulatory action will: 1) strengthen or erode the authority and rights of parents in the education, nurturing, and supervision of their children; 2) encourage or discourage economic self-sufficiency, self-pride, and the assumption of responsibility for oneself, one’s spouse, and one’s children and/or elderly parents; 3) strengthen or erode the marital commitment; and 4) increase or decrease disposable family income.

These amended regulations will not strengthen or erode the rights of parents in the education, nurturing, and supervision of their children. Parents have the right to refuse newborn screening for religious reasons. Parents also have the right to seek additional newborn screening testing outside of the state program if desired.

The amendments will not encourage or discourage economic self-sufficiency, self-pride, or the assumption of responsibility for oneself, one’s spouse, one’s children and/or elderly parents.

The amended regulations will not strengthen or erode marital commitment.

The amended regulations will not increase or decrease disposable family income.

Changes made since the proposed stage

*Please list all changes that made to the text of the proposed regulation and the rationale for the changes; explain the new requirements and what they mean rather than merely quoting the proposed text of the regulation. *Please put an asterisk next to any substantive changes.*

Section number	Requirement at proposed stage	What has changed	Rationale for change
12VAC5-71-210 A.	Requires hospitals to develop protocols for screening, timely evaluation, and timely referral of newborns with abnormal screening results that are in accordance with recommendations from the American Academy of Pediatrics (AAP).	Adds a specific reference to the AAP document that specifies screening protocols is included in the regulation.	1VAC7-10-160 states that an agency adopting textual matter by reference to another document, must include the name of the document, the publication date, version number, and publisher.
12VAC5-71-220 C.	States that the reasons that CCHD screening is not indicated shall be documented in the newborn’s medical record and identifies the primary reasons.	Clarifies that if CCHD screening <i>using pulse oximetry</i> is not performed the reason shall be documented. Adds parental or guardian refusal on the basis of religious practices or tenets as a basis for not conducting the screening.	Clarifies the text and makes it consistent with 12VAC5-71-260.
12VAC5-71-230 B.	Specifies how abnormal screening results are to be handled.	Specifies the timeframe as “immediately” in which abnormal results must be reported to the attending physician.	Provides greater specificity to the timeframe, and clarifies the urgency, for reporting abnormal results.

Public comment

Please summarize all comments received during the public comment period following the publication of the proposed stage, and provide the agency response. If no comment was received, please so indicate. Please distinguish between comments received on Town Hall versus those made in a public hearing or submitted directly to the agency or board.

Commenter	Comment	Agency response
TAilshire	Opposes practicing medicine from the Statehouse or General Assembly. Mandating tests adds to the costs of the health care system.	Although this screening is mandated by the Code of Virginia, the majority of hospitals are already including this as part of their newborn screening and it has been identified as a standard practice by the American Academy of Pediatrics.
Robin Gahan, American Heart Association	Support the addition of CCHD screening. This test is a low-cost, non-invasive test that detects over 90% of afflicted newborns.	VDH notes the support of the emergency regulations that are now in effect.

All changes made in this regulatory action

Please list all changes that are being proposed and the consequences of the proposed changes. Describe new provisions and/or all changes to existing sections. Explain the new requirements and what they mean rather than merely quoting the proposed text of the regulation

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
12VAC5-71-10	N/A	Includes definitions for words and terms that are used in the regulation.	Adds definitions for “Abnormal screening results”; “Critical congenital heart disease”; “CCHD screening”; “Echocardiogram”; “Licensed practitioner”; “Newborn nursery”; “Screening technology”; “Specialty level nursery”; and “Subspecialty level nursery”
12VAC5-71-30	N/A	The Virginia Newborn Screening System includes the Virginia Newborn Screening Program and the Virginia Early Hearing Detection and Intervention Program.	CCHD is added as a third element of the Virginia Newborn Screening System.
12VAC5-71-150	N/A	Care coordination services will be provided for Virginia residents who are diagnosed with selected heritable disorders or genetic diseases.	CCHD is added as a third diagnosis group that would make an individual eligible for care coordination services.

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
	12VAC5-71-210		<p>This is a new section requiring hospitals to develop protocols for screening, timely evaluation, and timely referral of newborns with abnormal screening results. The intent is to allow hospitals to develop their own protocols in three required areas.</p>
	12VAC5-71-220		<p>This is a new section requiring a licensed practitioner to perform the CCHD screening using pulse oximetry, and setting forth when the screening is to occur. If pulse oximetry screening is not performed, documentation requirements are set forth for the medical record. Hospitals shall develop screening protocols for specialty and sub-specialty nurseries.</p> <p>Intent is to ensure that qualified personnel perform the screening within the relevant time frame, and to set forth exceptions when pulse oximetry screening is not required.</p> <p>Intent is to permit hospitals with specialty and subspecialty nurseries to develop protocols for screening within those specialized units.</p>
	12VAC5-71-230		<p>This is a new section requiring all screening results to be entered into the medical record and the electronic birth certificate system. The section also requires health care providers to report abnormal screening results immediately and to evaluate the newborn in a timely manner. Newborns shall not be discharged unless a cause for the abnormal screening result has been determined or CCHD has been ruled out. Parents or guardians and the infant's primary care provider after discharge from the hospital shall be notified of any abnormal results and any diagnoses.</p> <p>Intent is to ensure that screening results are properly documented, responded to, and communicated to parents or guardians and the infant's primary care provider after discharge from the hospital.</p>
	12VAC5-71-		<p>This is a new section requiring hospitals</p>

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
	240		<p>to report individuals diagnosed with CCHD to VDH so that the newborn's parent or guardian may be referred to care coordination services through the Care Connection for Children.</p> <p>Intent is to refer parents and guardians of infants with CCHD to care coordination services.</p>
	12VAC5-71-250		<p>This is a new section specifying what documents shall be provided when requested by the VaCARES system at VDH, and specifying the confidentiality rules for these documents.</p> <p>Intent is to allow VDH to research final outcomes of abnormal CCHD screening results and evaluate screening activities in the state.</p>
	12VAC5-71-260		<p>This is a new section that permits parents to refuse CCHD screening based upon religious practices or tenets, and to specify that the hospital must report the refusal to VDH.</p> <p>Intent is to allow parents to refuse CCHD screening in accordance with their religious tenets, as specified in the authorizing legislation.</p>
12VAC5-191-260	N/A	The Virginia Newborn Screening System includes the Virginia Newborn Screening Program and the Virginia Early Hearing Detection and Intervention Program.	CCHD is added as a third element of the Virginia Newborn Screening System. The mission, scope of services, governing regulations, criteria, and goal of the screening are documented.