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Proposed Regulation
Agency Background Document

Agency name	Virginia Department of Health (VDH)
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 babies born in hospitals with a newborn nursery in Virginia are screened for CCHD
Date this document prepared	April 27, 2015

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 (preferably no more than 2 or 3 paragraphs) of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed.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.

These 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 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 Connections 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 proposed amendments would require a small number of additional hospitals to implement the 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 could be referred to the "Care Connections for Children" program to obtain care coordination services.

This regulatory action also includes proposed amendments to the State Plan for the 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

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 babies. A few babies 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.

The purpose of the proposed regulatory action is to ensure that all Virginia hospitals with newborn nurseries implement CCHD screening, and to ensure 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. A more detailed discussion is provided in the "Detail of changes" section below.

These proposed 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.
- 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 proposed 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 proposed amendments 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 proposed regulations.

Public participation

Please include a statement that in addition to any other comments on the proposal, the agency is seeking comments on the costs and benefits of the proposal and the impacts of the regulated community.

In addition to any other comments, the Board of Health is seeking comments on the costs and benefits of the proposal and the potential impacts of this regulatory proposal. Also, the Board is seeking information on impacts on small businesses as defined in § 2.2-4007.1 of the Code of Virginia. Information may include 1) projected reporting, recordkeeping and other administrative costs, 2) probable effect of the regulation on affected small businesses, and 3) description of less intrusive or costly alternative methods of achieving the purpose of the regulation.

Anyone wishing to submit written comments for the public comment file may do so by mail, email or fax to Dev Nair, 109 Governor Street, Richmond, Virginia 23219; 804-864-7662 (phone); 804-864-7380 (fax); or

Dev.Nair@vdh.virginia.gov. Comments may also be submitted through the Public Forum feature of the Virginia Regulatory Town Hall web site at: http://www.townhall.virginia.gov. Written comments must include the name and address of the commenter. In order to be considered, comments must be received by 11:59 pm on the last day of the public comment period.

A public hearing will not be held following the publication of this stage of this regulatory action.

Economic impact

Please identify the anticipated economic impact of the proposed new regulations or amendments to the existing regulation. When describing a particular economic impact, please specify which new requirement or change in requirement creates the anticipated economic impact.

Projected cost to the state to implement and enforce the proposed regulation, including: **a) fund source / fund detail; and** **b) a delineation of one-time versus on-going expenditures**	Actions to educate hospitals and develop a tracking and recording system for CCHD were supported by a CDC grant. There are no additional costs to the state to implement this regulation.
Projected cost of the new regulations or changes to existing regulations on localities.	There are no projected costs to localities for these new regulations.
Description of the individuals, businesses, or other entities likely to be affected by the new regulations or changes to existing regulations.	These regulations will impact infants that are born in Virginia hospitals with newborn nurseries (excluding those that are hospitalized in neonatal intensive care units [NICU]) as well as the hospitals themselves.
Agency's best estimate of the number of such entities that will be affected. Please include an estimate of the number of small businesses affected. Small business means a business entity, including its affiliates, that: a) is independently owned and operated and; b) employs fewer than 500 full-time employees or has gross annual sales of less than $6 million.	Virginia hospitals with newborn nurseries: 55 Infants born in these facilities annually (excluding NICU births): 70,000 – 75,000
All projected costs of the new regulations or changes to existing regulations for affected individuals, businesses, or other entities. Please be specific and include all costs including: **a) the projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses; and** **b) specify any costs related to the development of real estate for commercial or residential purposes that are a consequence of the proposed regulatory changes or new regulations.**	Screening infants for CCHD is considered a best practice and was adopted by most hospitals prior to the requirements enacted by the 2014 General Assembly. Additional reporting of screening results and confirmed cases that are required by these regulations occurs through existing systems (electronic birth certificate and VaCARES), therefore additional costs to implement these regulations are projected to be minimal.
Beneficial impact the regulation is designed to produce.	CCHD is a serious health condition affecting newborns that can result in death if not diagnosed and treated early. These regulations will assure that all newborns born in Virginia hospitals with newborn nurseries will be screened for CCHD prior to their discharge from the hospital.

	Approximately 200 newborns annually in Virginia have CCHD.

Alternatives

Please describe any viable alternatives to the proposal considered and the rationale used by the agency to select the least burdensome or intrusive alternative that meets the essential purpose of the action. Also, include discussion of less intrusive or less costly alternatives for small businesses, as defined in § 2.2-4007.1 of the Code of Virginia, of achieving the purpose of the regulation.

None. The Acts of Assembly of 2014 required the Board to promulgate regulations to implement the provisions of House Bill 387 and Senate Bill 183. Section 32.1-65.1 of the Code of Virginia states that the Board of Health shall require every hospital in Virginia having a newborn nursery to screen infants for critical congenital heart disease. There are no viable alternatives to the proposed amendments.

Regulatory flexibility analysis

Pursuant to § 2.2-4007.1B of the Code of Virginia, please describe the agency's analysis of alternative regulatory methods, consistent with health, safety, environmental, and economic welfare, that will accomplish the objectives of applicable law while minimizing the adverse impact on small business. Alternative regulatory methods include, at a minimum: 1) the establishment of less stringent compliance or reporting requirements; 2) the establishment of less stringent schedules or deadlines for compliance or reporting requirements; 3) the consolidation or simplification of compliance or reporting requirements; 4) the establishment of performance standards for small businesses to replace design or operational standards required in the proposed regulation; and 5) the exemption of small businesses from all or any part of the requirements contained in the proposed regulation.

The proposed amendments do not directly impact small businesses. The Acts of Assembly of 2014 required the Board to promulgate regulations to implement the provisions of House Bill 387 and Senate Bill 183. Section 32.1-65.1 of the Code of Virginia states that the Board of Health shall require every hospital in Virginia having a newborn nursery to screen infants for critical congenital heart disease.

Periodic review and small business impact review report of findings

If you are using this form to report the result of a periodic review/small business impact review that was announced during the NOIRA stage, please indicate whether the regulation meets the criteria set out in Executive Order 17 (2014), e.g., is necessary for the protection of public health, safety, and welfare, and is clearly written and easily understandable. In addition, as required by 2.2-4007.1 E and F, please include a discussion of the agency's consideration of: (1) the continued need for the regulation; (2) the nature of complaints or comments received concerning the regulation from the public; (3) the complexity of the regulation; (4) the extent to the which the regulation overlaps, duplicates, or conflicts with federal or state law or regulation; and (5) the length of time since the regulation has been evaluated or the degree to which technology, economic conditions, or other factors have changed in the area affected by the regulation.

N/A

Public comment

Please summarize all comments received during the public comment period following the publication of the NOIRA, and provide the agency response.

Commenter	Comment	Agency response
Robert Shor, MD, FACC, VA Chapter American College of Cardiology	The Virginia Chapter of the American College of Cardiology (the Chapter) supports the Emergency Regulation Governing Virginia Newborn Screening Services published in the Virginia Register of Regulations, January 26, 2015. This Emergency Regulation enhances the quality of life for children born in Virginia hospitals. Pulse oximetry screening is a simple, effective, inexpensive, and noninvasive test. The Chapter is particularly pleased with the definition of screening technology which "means pulse oximetry testing in the right hand and either foot". The Chapter strongly approves that the definition allows for future contingencies.	VDH notes the support of the emergency regulations that are now in effect.
Amy Hewett, American Heart Association	The American Heart Association strongly supports the Department's new regulations that add critical congenital heart disease (CCHD) screening using pulse oximetry testing in the Commonwealth's Newborn Screening System. With this new regulation, Virginia joins dozens of other states that have taken the important steps to require this life-saving screening for newborns. The simple pulse oximetry test can detect CCHD in more than 90 percent of afflicted newborns. Moreover, pulse oximetry screening is a low-cost, non-invasive bedside diagnostic test that can be completed in as little as 45 seconds.	VDH notes the support of the emergency regulations that are now in effect.

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.

The proposed amendment to the regulation 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 proposed amendment 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 proposed amendment will not strengthen or erode marital commitment.

The proposed amendment will not increase or decrease disposable family income.

Detail of changes

*Please list all changes that are being proposed and the consequences of the proposed changes; explain the new requirements and what they mean rather than merely quoting the proposed text of the regulation. If the proposed regulation is a new chapter, describe the intent of the language and the expected impact. Please describe the difference between existing regulation(s) and/or agency practice(s) and what is being proposed in this regulatory action. If the proposed regulation is intended to replace an emergency regulation, please list separately: (1) all differences between the **pre**-emergency regulation and this proposed regulation; and 2) only changes made since the publication of the emergency regulation.*

For changes to existing regulation(s), use this chart:

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change, intent, rationale, and likely impact of proposed requirements
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.
12VAC5-191-260	N/A	The Virginia Newborn Screening System includes	CCHD is added as a third element of the Virginia Newborn Screening System. The

		the Virginia Newborn Screening Program and the Virginia Early Hearing Detection and Intervention Program.	mission, scope of services, governing regulations, criteria, and goal of the screening are documented.

If a new regulation is being promulgated, use this chart:

Section number	Proposed requirements	Other regulations and law that apply	Intent and likely impact of proposed requirements
12VAC5-71-210	This is a new section requiring hospitals to develop protocols for screening, timely evaluation, and timely referral of newborns with abnormal screening results.	N/A	Intent is to allow hospitals to develop their own protocols in three required areas.
12VAC5-71-220	This is a new section requiring a licensed practitioner to 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 shall develop screening protocols for specialty and sub-specialty nurseries.	N/A	Intent is to ensure that qualified personnel perform the screening within the relevant time frame, and to set forth exceptions when screening is not required. Intent is to permit hospitals with specialty and subspecialty nurseries to develop protocols for screening within those specialized units.
12VAC5-71-230	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 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.	N/A	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.
12VAC5-71-240	This is a new section requiring hospitals to report individuals diagnosed with CCHD to VDH so that the	N/A	Intent is to refer parents and guardians of infants with CCHD to care coordination services.

	newborn's parent or guardian may be referred to care coordination services through the Care Connection for Children.		
12VAC5-71-250	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.	N/A	Intent is to allow VDH to research final outcomes of abnormal CCHD screening results and evaluate screening activities in the state.
12VAC5-71-260	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.	N/A	Intent is to allow parents to refuse CCHD screening in accordance with their religious tenets, as specified in the authorizing legislation.

Summary of changes made to regulatory language from the emergency to the proposed stage:

VDH has made some changes to the regulatory text from the emergency/NOIRA stage to the proposed stage. These revisions are relatively minor and are generally intended to simplify and/or clarify text. These changes are outlined below:

- The emergency regulations listed definitions for the new CCHD requirements in their own section, 12VAC5-71-200. These have been incorporated into the general definitions section in 12VAC5-71-10.
- The definition of "Newborn" was changed to state a person in the first 28 days of life who was born in Virginia. The term "or on federal property in Virginia" has been stricken from the definition of newborn that is in the emergency regulations.
- There was a change to the reference provided for the definition of "Specialty level nursery"
- The term "premature" was removed from 12VAC5-71-220 C.3 to clarify that the regulations would not apply to any infant that is in a specialty or sub-specialty nursery, regardless of whether or not they are premature.
- Section 12VAC5-71-230 A added two additional elements to be recorded in the electronic birth certificate; pulse oximetry values, and whether the newborn was not screened pursuant to 12VAC5-71-220 C or 12VAC5-71-260.
- 12VAC5-71-240 A. was modified to change the term "under these regulations" to "under 12VAC5-71-210 through 12VAC5-71-260" to clarify that this only applies to infants diagnosed with CCHD.