



Virginia
Regulatory
Town Hall

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Emergency Regulation and Notice of Intended Regulatory Action (NOIRA) Agency Background Document

Agency name	Virginia Department of Health (VDH)
Virginia Administrative Code (VAC) citation	12VAC5-71
Regulation title	Regulations Governing Virginia Newborn Screening Services
Action title	Amend regulations to add critical congenital heart disease (CCHD) to the Virginia Newborn Screening System
Date this document prepared	June 9, 2014

This form is used when an agency wishes to promulgate an emergency regulation (to be effective for up to one year), as well as publish a Notice of Intended Regulatory Action (NOIRA) to begin the process of promulgating a permanent replacement regulation.

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 14 (2010) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual*.

Preamble

The APA (Code of Virginia § 2.2-4011) states that agencies may adopt emergency regulations in situations in which Virginia statutory law or the appropriation act or federal law or federal regulation requires that a regulation be effective in 280 days or less from its enactment, and the regulation is not exempt under the provisions of subdivision A. 4. of § 2.2-4006.

Legislation enacted during the 2014 legislative session requires VDH to implement regulations relating to screening for critical congenital heart disease: HB387, which was signed by the Governor on February 20, 2014, and SB183, which was signed by the Governor on March 5, 2014. Both bills require VDH to promulgate regulations for CCHD screening within 280 days of enactment.

The legislation requires that the regulations include provisions to implement CCHD screening for all babies born in hospitals with newborn nurseries. Both bills also required VDH to convene a workgroup to provide information and recommendations for the development of the regulations.

Most hospitals in Virginia are already voluntarily performing this screening. The regulations would require a small number of additional hospitals to implement the screening. The regulations 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.

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.

HB387, which was signed by the Governor on February 20, 2014, and SB183, which was signed by the Governor on March 5, 2014, both require VDH to promulgate regulations requiring CCHD screening within 280 days of enactment.

Section 2.2-4011 of the Code of Virginia states that agencies may adopt emergency regulations in situations in which Virginia statutory law or the appropriation act or federal law or federal regulation requires that a regulation be effective in 280 days or less from its enactment, and the regulation is not exempt under the provisions of subdivision A. 4. of § 2.2-4006.

Purpose

Please describe the subject matter and intent of the planned regulatory action. Also include a brief explanation of the need for and the goals of the new or amended regulation.

In April, 2012, Governor McDonnell issued an Executive Order to develop a plan to implement screening for CCHD. Subsequently, VDH received a three-year Health Resources and Services Administration grant to develop a pilot screening project. The Governor's Work Group on CCHD convened soon after, followed by the development of a pilot project that was launched in the fall of 2012, implementing CCHD screening at six birthing hospitals across the state.

The pilot project was very successful, and additional Virginia hospitals voluntarily began CCHD screening. The purpose of this regulation 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.

Need

Please detail the specific reasons why the agency has determined that the proposed regulatory action is essential to protect the health, safety, or welfare of citizens. In addition, delineate any potential issues that may need to be addressed as the regulation is developed.

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, or 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 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 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.

Substance

Please detail any changes that will be proposed. Please outline new substantive provisions, all substantive changes to existing sections, or both where appropriate.

Changes to existing regulations:

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change, intent, and likely impact of proposed requirements
5-71-30	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.
5-71-200	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 that would make an individual eligible for care coordination services.
5-191-260	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.

New Sections:

Section number	Proposed requirements	Other regulations and law that apply	Intent and likely impact of proposed requirements
5-71-200	This is a new definition section for the CCHD requirements.	N/A	Intent is to make the regulation as clear as possible.

5-71-210	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.
5-71-220	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	<p>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.</p> <p>Intent is to permit hospitals with specialty and subspecialty nurseries to develop protocols for screening within those specialized units.</p>
5-71-230	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 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.	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.
5-71-240	This is a new section requiring hospitals 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.	N/A	Intent is to refer parents and guardians of infants with CCHD to care coordination services.
5-71-250	This is a new section specifying what documents shall be provided when requested by the VaCARES	N/A	Intent is to allow VDH to research final outcomes of abnormal CCHD screening results and evaluate screening

	system at VDH, and specifying the confidentiality rules for these documents.		activities in the state.
5-71-260	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.

Alternatives

Please describe all viable alternatives to the proposed regulatory action that have been or will be considered to meet the essential purpose of the action. Also describe the process by which the agency has considered or will consider other alternatives for achieving the need in the most cost-effective manner.

There are no alternatives to this regulatory action because VDH is required to promulgate regulations to meet the statutory mandate. VDH convened a group of 20 stakeholders to provide information and recommendations for the regulations, and to help achieve the statutory mandate in the most efficient, cost-effective manner.

Public participation

Please indicate the agency is seeking comments on the intended regulatory action, to include ideas to assist the agency in the development of the proposal and the costs and benefits of the alternatives stated in this notice or other alternatives. Also, indicate whether a public meeting is to be held to receive comments on this notice.

Please also indicate, pursuant to your Public Participation Guidelines, whether a Regulatory Advisory Panel or a Negotiated Rulemaking Panel has been used in the development of the emergency regulation and whether it will also be used in the development of the permanent regulation.

The agency is seeking comments on the regulation that will permanently replace this emergency regulation, including but not limited to 1) ideas to be considered in the development of the permanent replacement regulation, 2) the costs and benefits of the alternatives stated in this background document or other alternatives and 3) the potential impacts of the regulation.

The agency is also 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) the probable effect of the regulation on affected small businesses, and 3) the description of less intrusive or costly alternatives for achieving the purpose of the regulation.

Anyone wishing to submit comments may do so via the Regulatory Town Hall website (<http://www.townhall.virginia.gov>), or by mail, email, or fax to Emily McClellan, 109 Governor Street, Richmond, Virginia 23219, phone 804-786-7249, fax number 804-864-7380, or email Emily.McClellan@vdh.virginia.gov. Written comments must include the name and address of the commenter. In order to be considered, comments must be received by midnight on the last day of the public comment period.

Pursuant to 12VAC5-11, a regulatory advisory panel was used to assist in the development of the emergency regulation and will also be used to assist in the development of the permanent regulation. Anyone interested in serving on this panel should contact Emily McClellan, 109 Governor Street, Richmond, Virginia 23219, phone 804-786-7249, fax number 804-864-7380, or email Emily.McClellan@vdh.virginia.gov.

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

Family impact

Assess the potential impact of the proposed 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 regulations and amendments will not strengthen or erode the authority and rights of parents in the education, nurturing, and supervision of their children. Parents have the right to refuse CCHD 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.