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Fast-Track Regulation Agency Background Document

Agency name	State Board of Health
Virginia Administrative Code (VAC) Chapter citation(s)	12VAC5-71
VAC Chapter title(s)	Regulations Governing Virginia Newborn Screening Services
Action title	Amend Regulations Following Periodic Review
Date this document prepared	October 10, 2024

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Order 19 (2022) (EO 19), any instructions or procedures issued by the Office of Regulatory Management (ORM) or the Department of Planning and Budget (DPB) pursuant to EO 19, the Regulations for Filing and Publishing Agency Regulations (1 VAC 7-10), and the *Form and Style Requirements for the Virginia Register of Regulations and Virginia Administrative Code*.

Brief Summary

Provide a brief summary (preferably no more than 2 or 3 paragraphs) of this regulatory change (i.e., new regulation, amendments to an existing regulation, or repeal of an existing regulation). Alert the reader to all substantive matters. If applicable, generally describe the existing regulation.

This regulatory action seeks to amend 12VAC5-71 - Regulations Governing Virginia Newborn Screening Services by repealing sections concerning Critical Congenital Heart Disease (CCHD) newborn screening and creating a new chapter (12VAC5-72) to house the CCHD newborn screening regulations in order to improve clarity of regulatory requirements. The action also provides minor updates to reflect current best practices and scientific information relevant to CCHD. Additionally, this action amends both 12VAC5-71 and the newly created 12VAC5-72 to provide stylistic updates to improve the clarity of the regulations and ensure compliance with the *Virginia Register of Regulations Form, Style and Procedure Manual*.

The existing Critical Congenital Heart Disease (CCHD) newborn screening regulations are housed alongside the newborn blood spot screening regulations in Chapter 71 of the Virginia Administrative Code. These regulations outline regulatory requirements for CCHD protocols, screenings, results reporting, care coordination, records, and screening refusals. VDH introduced the CCHD regulations in 2014 and the regulations became effective in 2016, but they have not been updated since that time.

While the dried blood spot and CCHD newborn screening regulations are currently housed in the same chapter, a separate regulatory chapter exists for the hearing newborn screening program. Because regulations for both dried blood spot newborn screening and CCHD newborn screening are included in 12VAC5-71 confusion from regulants, specifically with the Out-of-Hospital (OOH) birth community, has been reported. While dried blood spot regulations apply to all births (including OOH births and OOH birth providers), CCHD regulations do not apply to OOH births or birth providers. Promulgating CCHD regulations into their own chapter would provide consistency across the newborn screening programs and clarify roles and responsibilities of the health care providers for the different newborn screenings.

Acronyms and Definitions

Define all acronyms used in this form, and any technical terms that are not also defined in the “Definitions” section of the regulation.

AAP – American Academy of Pediatrics

CCHD – Critical Congenital Heart Disease

OOH – Out of Hospital

VDH – Virginia Department of Health

Statement of Final Agency Action

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 State Board of Health approved these Fast Track Amendments to the Regulations Governing Virginia Newborn Screening Regulations (12VAC5-71) at the December 5th, 2024 Board of Health Meeting.

Mandate and Impetus

Identify the mandate for this regulatory change and any other impetus that specifically prompted its initiation (e.g., new or modified mandate, petition for rulemaking, periodic review, or board decision). For purposes of executive branch review, “mandate” has the same meaning as defined in the ORM procedures, “a directive from the General Assembly, the federal government, or a court that requires that a regulation be promulgated, amended, or repealed in whole or part.”

Consistent with Virginia Code § 2.2-4012.1, also explain why this rulemaking is expected to be noncontroversial and therefore appropriate for the fast-track rulemaking process.

In 2014, VDH proposed regulations for CCHD newborn screening to be added to 12VAC5-71, adding sections 12VAC5-71-210 to 12VAC5-71-260. These regulations were initially adopted as emergency regulations in 2015, and later adopted as permanent regulations in October 2016.

Pursuant to Executive Order 19 (2022) the Office of Family Health Services (OFHS) conducted a periodic review of 12VAC5-71 – Regulations Governing Virginia Newborn Screening Services. This regulatory action is intended to implement the Board’s decision in the chapter’s most recent periodic review. The periodic review, filed on July 29, 2021, resulted in a decision to amend the regulations. This proposed regulatory action follows the recommendation of that periodic review.

Consistent with *Virginia Code § 2.2-4012.1*, this rulemaking is expected to be noncontroversial because it is moving existing regulations into a new chapter and making minor edits that will not substantially affect existing requirements or the stakeholders who are required to follow these regulations.

Legal Basis

Identify (1) the promulgating agency, and (2) the state and/or federal legal authority for the regulatory change, including the most relevant citations to the Code of Virginia and Acts of Assembly chapter number(s), if applicable. Your citation must include a specific provision, if any, authorizing the promulgating agency to regulate this specific subject or program, as well as a reference to the agency's overall regulatory authority.

§ 32.1-12 of the Code of Virginia authorizes the State Board of Health to make, adopt, promulgate and enforce regulations.

§ 32.1-65.1 of the Code of Virginia requires Critical Congenital Heart Disease newborn screening to be conducted on every infant born in the Commonwealth of Virginia based on standards set forth by the American Academy of Pediatrics (AAP).

§ 32.1-67 of the Code of Virginia requires the Board of Health to promulgate regulations as necessary to implement Newborn Screening Services.

Purpose

Explain the need for the regulatory change, including a description of: (1) the rationale or justification, (2) the specific reasons the regulatory change is essential to protect the health, safety or welfare of citizens, and (3) the goals of the regulatory change and the problems it is intended to solve.

§ 32.1-65 of the Code of Virginia sets forth requirements for mandatory newborn screening tests for all infants born in the Commonwealth, "in order to prevent intellectual disability and permanent disability or death."

§ 32.1-65.1 of the Code of Virginia directs the Board to "require every hospital in the Commonwealth having a newborn nursery to perform a critical congenital heart defect screening test using pulse oximetry or other Board-approved screening test that is based on standards set forth by the American Academy of Pediatrics on every newborn in its care when such infant is at least 24 hours old but no more than 48 hours old or, in cases in which the infant is discharged from the hospital prior to reaching 24 hours of age, prior to discharging the infant."

§ 32.1-67 of the Code of Virginia requires the Board to promulgate regulations necessary to implement Newborn Screening Services and the Children with Special Health Care Needs Program.

The proposed regulatory change is needed to provide clarity within the newborn screening programs, specifically, clarifying roles and responsibilities of health care providers based on different newborn screenings. There has been confusion reported by Out-of-Hospital (OOH) providers regarding the newborn screening regulations as written, as not all regulations are applicable to all birth providers.

Substance

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.

The fast track regulatory amendments will remove sections 12VAC5-71-210 to 12VAC5-71-260, relating to CCHD newborn screenings, and create a new chapter, 12VAC5-72, to house those regulations.

Additionally, the fast track amendments update and add to existing definitions applicable to the new chapter; update regulatory language to provide consistency and compliance with the Virginia Register’s style requirements; update language throughout 12VAC5-71 and the newly created 12VAC5-72 to ensure alignment with the most recent best practices and scientific information on CCHD; more clearly identify the CCHD Newborn Screening Program within VDH as the program assigned to oversee the mandate and regulations; clarify the process for parents and providers to document refusals of screenings; and add additional information regarding confidentiality of the screening results.

Issues

Identify the issues associated with the regulatory change, 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, include a specific statement to that effect.

The primary advantage to the public, agency, Commonwealth, and other relevant stakeholders is improved clarity of the regulations for regulants, including hospitals and healthcare providers. Clarifying language addresses the roles and responsibilities of providers related to newborn screening services, specifically screening for CCHD and reporting results of CCHD newborn screenings.

There are no obvious disadvantages to the public, agency, Commonwealth, and other relevant stakeholders for the adoption of this regulatory change.

Requirements More Restrictive than Federal

Identify and describe any requirement of the regulatory change which is more restrictive than applicable federal requirements. Include a specific citation for each applicable federal requirement, and 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 specific statement to that effect.

There are no applicable federal requirements.

Agencies, Localities, and Other Entities Particularly Affected

Consistent with § 2.2-4007.04 of the Code of Virginia, identify any other state agencies, localities, or other entities particularly affected by the regulatory change. Other entities could include local partners such as tribal governments, school boards, community services boards, and similar regional organizations. “Particularly affected” are those that are likely to bear any identified disproportionate material impact which would not be experienced by other agencies, localities, or entities. “Locality” can refer to either local governments or the locations in the Commonwealth where the activities relevant to the regulation or regulatory change are most likely to occur. If no agency, locality, or entity is particularly affected, include a specific statement to that effect.

Other State Agencies Particularly Affected

There is no other state agency particularly affected by this regulation change.

Localities Particularly Affected

There are no known localities particularly affected by this regulation change.

Other Entities Particularly Affected

There are no known other entities particularly affected by this regulation change.

Economic Impact

Consistent with § 2.2-4007.04 of the Code of Virginia, identify all specific economic impacts (costs and/or benefits), anticipated to result from the regulatory change. When describing a particular economic impact, specify which new requirement or change in requirement creates the anticipated economic impact. Keep in mind that this is the proposed change versus the status quo.

Impact on State Agencies

<i>For your agency:</i> projected costs, savings, fees or revenues resulting from the regulatory change, including: a) fund source / fund detail; b) delineation of one-time versus on-going expenditures; and c) whether any costs or revenue loss can be absorbed within existing resources	The regulatory change has no economic impact on VDH.
<i>For other state agencies:</i> projected costs, savings, fees or revenues resulting from the regulatory change, including a delineation of one-time versus on-going expenditures.	This regulatory change has no economic impact on other state agencies.
<i>For all agencies:</i> Benefits the regulatory change is designed to produce.	This regulatory change is intended to improve the health and well-being of individuals in Virginia by improving clarity regarding CCHD screening and reporting requirements, which will in turn allow VDH to better identify children with CCHD who might benefit from support services.

Impact on Localities

If this analysis has been reported on the ORM Economic Impact form, indicate the tables (1a or 2) on which it was reported. Information provided on that form need not be repeated here.

Projected costs, savings, fees or revenues resulting from the regulatory change.	This regulatory change has no economic impact on localities.
Benefits the regulatory change is designed to produce.	This regulatory change is intended to improve the health and well-being of individuals in Virginia by improving clarity regarding CCHD screening and reporting requirements, which will in turn allow VDH to better identify children with CCHD who might benefit from support services.

Impact on Other Entities

If this analysis has been reported on the ORM Economic Impact form, indicate the tables (1a, 3, or 4) on which it was reported. Information provided on that form need not be repeated here.

Description of the individuals, businesses, or other entities likely to be affected by the regulatory change. If no other entities will be affected, include a specific statement to that effect.	No entities are known to be particularly affected by the proposed regulation change.
Agency's best estimate of the number of such entities that will be affected. 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.	\$0
All projected costs for affected individuals, businesses, or other entities resulting from the regulatory change. Be specific and include all costs including, but not limited to: a) projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses; b) specify any costs related to the development of real estate for commercial or residential purposes that are a consequence of the regulatory change; c) fees; d) purchases of equipment or services; and e) time required to comply with the requirements.	\$0
Benefits the regulatory change is designed to produce.	\$0

Alternatives to Regulation

Describe any viable alternatives to the regulatory change that were considered, and the rationale used by the agency to select the least burdensome or intrusive alternative that meets the essential purpose of the regulatory change. 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 regulatory change.

Alternatives to this regulatory change are limited to maintaining the status quo – not amending the regulations. As the regulations as written may cause confusion with regard to provider duties and responsibilities as they relate to newborn screenings, the Board has determined that amendments are necessary.

If this analysis has been reported on the ORM Economic Impact form, indicate the tables on which it was reported. Information provided on that form need not be repeated here.

Regulatory Flexibility Analysis

Consistent with § 2.2-4007.1 B of the Code of Virginia, 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) establishing less stringent compliance or reporting requirements; 2) establishing less stringent schedules or deadlines for compliance or reporting requirements; 3) consolidation or simplification of compliance or reporting requirements; 4) establishing 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 regulatory change.

There are no known alternatives to the regulatory change. The regulations only require what is necessary for hospitals and providers to do regarding newborn screening and reporting of CCHD in order to be compliant with the Code of Virginia and also ensure that the agency is effectively tracking CCHD and providing supports for families whose children have confirmed CCHD.

If this analysis has been reported on the ORM Economic Impact form, indicate the tables on which it was reported. Information provided on that form need not be repeated here.

Public Participation

Indicate how the public should contact the agency to submit comments on this regulation, and whether a public hearing will be held, by completing the text below.

Consistent with § 2.2-4011 of the Code of Virginia, if an objection to the use of the fast-track process is received within the 30-day public comment period from 10 or more persons, any member of the applicable standing committee of either house of the General Assembly or of the Joint Commission on Administrative Rules, the agency shall: 1) file notice of the objections with the Registrar of Regulations for publication in the Virginia Register and 2) proceed with the normal promulgation process with the initial publication of the fast-track regulation serving as the Notice of Intended Regulatory Action.

If you are objecting to the use of the fast-track process as the means of promulgating this regulation, please clearly indicate your objection in your comment. Please also indicate the nature of, and reason for, your objection to using this process.

The Virginia Department of Health is providing an opportunity for comments on this regulatory proposal, including but not limited to (i) the costs and benefits of the regulatory proposal and any alternative approaches, (ii) the potential impacts of the regulation, and (iii) the agency's regulatory flexibility analysis stated in this background document.

Anyone wishing to submit written comments for the public comment file may do so through the Public Comment Forums feature of the Virginia Regulatory Town Hall web site at: <https://townhall.virginia.gov>. Comments may also be submitted by mail, email or fax to:

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In order to be considered, comments must be received by 11:59 pm on the last day of the public comment period.

Detail of Changes

List all regulatory changes and the consequences of the changes. Explain the new requirements and what they mean rather than merely quoting the text of the regulation. For example, describe the intent of the language and the expected impact. Describe the difference between existing requirement(s) and/or agency practice(s) and what is being proposed in this regulatory change. Use all tables that apply, but delete inapplicable tables.

If an existing VAC Chapter(s) is being amended or repealed, use Table 1 to describe the changes between existing VAC Chapter(s) and the proposed regulation. If existing VAC Chapter(s) or sections are being repealed and replaced, ensure Table 1 clearly shows both the current number and the new number for each repealed section and the replacement section.

Table 1: Changes to Existing VAC Chapter(s)

Current chapter-section number	New chapter-section number, if applicable	Current requirements in VAC	Change, intent, rationale, and likely impact of new requirements
12VAC5-71-10		Definitions	<p>Change: Remove unnecessary definitions for terms no longer appearing in 12VAC5-71 – “Abnormal screening results”, “Echocardiogram”, “population-based”, and “Screening Technology”</p> <p>Intent: Provide clarity and consistency throughout the regulations</p> <p>Rationale: Clear and consistent definitions ensure accurate interpretation of the regulations.</p> <p>Likely Impact: Improvements in readability and comprehension of the regulations by regulations</p>
12VAC5-71-150		Responsibilities of the Care Connection for Children network	<p>Change: Remove critical congenital heart disease as a service provided by the Care Connection for Children network</p>

			<p>Intent: Remove CCHD from 12VAC5-71 and move reference to 12VAC5-72</p> <p>Rationale: Creating a new chapter to exclusively house CCHD regulations will clarify regulations.</p> <p>Likely Impact: Greater readability and comprehension of the regulations.</p>
12VAC5-71-210		Critical congenital heart disease screening protocols	<p>Change: Repeal section</p> <p>Intent: Move CCHD regulations to new chapter.</p> <p>Rationale: Creating a new chapter to exclusively house CCHD regulations will clarify regulations.</p> <p>Likely Impact: Improved clarity of the regulations</p>
12VAC5-71-220		Critical congenital heart disease screening	<p>Change: Repeal section</p> <p>Intent: Move CCHD regulations to new chapter.</p> <p>Rationale: Creating a new chapter to exclusively house CCHD regulations will clarify regulations.</p> <p>Likely Impact: Improved clarity of the regulations.</p>
12VAC5-71-230		Critical congenital heart disease screening results.	<p>Change: Repeal section</p> <p>Intent: Move CCHD regulations to new chapter.</p> <p>Rationale: Creating a new chapter to exclusively house CCHD regulations will clarify regulations.</p> <p>Likely Impact: Improved clarity of the regulations</p>
12VAC5-71-240		Referral for care coordination	<p>Change: Repeal section</p> <p>Intent: Move CCHD regulations to new chapter.</p>

			<p>Rationale: Creating a new chapter to exclusively house CCHD regulations will clarify regulations.</p> <p>Likely Impact: Improved clarity of the regulations</p>
12VAC5-71-250		Critical congenital heart disease screening records	<p>Change: Repeal section</p> <p>Intent: Move CCHD regulations to new chapter.</p> <p>Rationale: Creating a new chapter to exclusively house CCHD regulations will clarify regulations.</p> <p>Likely Impact: Improved clarity of the regulations.</p>
12VAC5-71-260		Parent or guardian refusal for screening.	<p>Change: Repeal section</p> <p>Intent: Move CCHD regulations to new chapter.</p> <p>Rationale: Creating a new chapter to exclusively house CCHD regulations will clarify regulations.</p> <p>Likely Impact: Improved clarity of the regulations</p>
	12VAC5-72-10	Definitions	<p>Change: Add definitions for newly created Chapter</p> <p>Update definition for negative (pass) to continue to align with recommendations from the American Academy for Pediatrics (2025)</p> <p>Intent: Provide clear usage of words and terms for 12VAC5-72</p> <p>Rationale: Clearly defining words and terms used throughout the chapter will prevent confusion and improve readability and comprehension.</p>

			<p>Likely Impact: Clearly understandable regulations</p>
	12VAC5-72-20	Critical congenital heart disease screening protocols	<p>Change: Add section containing regulations from 12VAC5-71-210. Formatting changes to adhere to the Virginia Register style guide. Removed referenced guidance document, as it is not longer applicable.</p> <p>Intent: Move regulations from 12VAC5-71 into 12VAC5-72. Improve readability and compliance with the Virginia Register of Regulations Form and Style guide. Remove unnecessary references to documents.</p> <p>Rationale: Delineating regulations based on services provided may result in improved clarity and reduce confusion of regulants.</p> <p>Likely Impact: Improved clarity and consistency of the regulations.</p>
	12VAC5-72-30	Critical congenital heart disease screening	<p>Change: Add section containing regulations from 12VAC5-71-220. Formatting changes to adhere to the Virginia Register style guide. Updated reference to CCHD new section. Specified responsible party for screening procedures. Consolidated and clarified information.</p> <p>Intent: Move regulations from 12VAC5-71 into 12VAC5-72. Improve readability and compliance with the Virginia Register of Regulations Form and Style guide.</p> <p>Rationale: Delineating regulations based on services provided may result in improved clarity and reduce confusion of regulants.</p> <p>Likely Impact: Improved clarity and consistency of the regulations.</p>

	12VAC5-72-40	Critical congenital heart disease screening results	<p>Change: Add section containing regulations from 12VAC5-71-230. Formatting changes to adhere to the Virginia Register style guide. Updated reference to CCHD new section. Consolidated and clarified information.</p> <p>Intent: Move regulations from 12VAC5-71 into 12VAC5-72. Improve readability and compliance with the Virginia Register of Regulations Form and Style guide.</p> <p>Rationale: Delineating regulations based on services provided may result in improved clarity and reduce confusion of regulants.</p> <p>Likely Impact: Improved clarity and consistency of the regulations.</p>
	12VAC5-72-50	Provides conditions under which a referral for care coordination should be made	<p>Change: Add section containing regulations from 12VAC5-71-240. Formatting changes to adhere to the Virginia Register style guide. Updated reference to CCHD new section. Consolidated and clarified information.</p> <p>Intent: Move regulations from 12VAC5-71 into 12VAC5-72. Improve readability and compliance with the Virginia Register of Regulations Form and Style guide. Remove unnecessary references to documents.</p> <p>Rationale: Delineating regulations based on services provided may result in improved clarity and reduce confusion of regulants.</p> <p>Likely Impact: Improved clarity and consistency of the regulations.</p>
	12VAC5-72-60	Provides CCHD screening program information that hospitals	<p>Change: Add section containing regulations from 12VAC5-71-240. Formatting changes to adhere to the</p>

		<p>must make available upon request.</p>	<p>Virginia Register style guide. Updated reference to CCHD new section. Consolidated and clarified information. Clarified who will receive the information. Removed repetitive information.</p> <p>Intent: Move regulations from 12VAC5-71 into 12VAC5-72. Improve readability and compliance with the Virginia Register of Regulations Form and Style guide.</p> <p>Rationale: Delineating regulations based on services provided may result in improved clarity and reduce confusion of regulants.</p> <p>Likely Impact: Improved clarity and consistency of the regulations.</p>
	<p>12VAC5-72-70</p>	<p>Provides for refusal of screening by a parent or guardian in certain situations</p>	<p>Change: Add section containing regulations from 12VAC5-71-260. Formatting changes to adhere to the Virginia Register style guide. Specified responsible party for screening procedures and process for documenting the refusal.</p> <p>Intent: Move regulations from 12VAC5-71 into 12VAC5-72. Improve readability and compliance with the Virginia Register of Regulations Form and Style guide.</p> <p>Rationale: Delineating regulations based on services provided may result in improved clarity and reduce confusion of regulants.</p> <p>Likely Impact: Improved clarity and consistency of the regulations</p>
	<p>12VAC5-72-80</p>	<p>Provides the responsibilities of the Care Connection for Children network</p>	<p>Change: Add section containing certain regulations from 12VAC5-71-150. Formatting changes to adhere to the Virginia Register style guide.</p>

			<p>Intent: Move regulations from 12VAC5-71 into 12VAC5-72. Improve readability and compliance with the Virginia Register of Regulations Form and Style guide.</p> <p>Rationale: Delineating regulations based on services provided may result in improved clarity and reduce confusion of regulants.</p> <p>Likely Impact: Improved clarity and consistency of the regulations.</p>
	12VAC5-72-90	Procedures to maintain confidentiality of information	<p>Change: Add section containing certain regulations from 12VAC5-71-190. Formatting changes to adhere to the Virginia Register style guide.</p> <p>Intent: Move regulations from 12VAC5-71 into 12VAC5-72. Improve readability and compliance with the Virginia Register of Regulations Form and Style guide.</p> <p>Rationale: Delineating regulations based on services provided may result in improved clarity and reduce confusion of regulants.</p> <p>Likely Impact: Improved clarity and consistency of the regulations.</p>
	FORMS	Provides for Documents Incorporated by Reference (DIBR)	<p>Change: Add DIBRs necessary for this chapter</p>