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Fast-Track Regulation
Agency Background Document

Agency name	Virginia Department of Health
Virginia Administrative Code (VAC) Chapter citation(s)	12VAC5-191
VAC Chapter title(s)	State Plan for Children with Special Health Care Needs
Action title	Promulgate regulations to implement an adult comprehensive sickle cell clinic network.
Date this document prepared	September 21, 2020

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Order 14 (as amended, July 16, 2018), the Regulations for Filing and Publishing Agency Regulations (1VAC7-10), 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.

The intent of the proposed action is to promulgate a new regulation to implement an adult comprehensive sickle cell clinic network. During the 2020 General Assembly session, House Bill 907 amended a subsection of §32.1-68 of the Code of Virginia to include language specifying that the voluntary program for the screening of sickle cell disease or sickle cell traits is for adults and children. The bill also includes a subsection of §32.1-68, mandating the Board of Health to adopt regulations to implement an adult comprehensive sickle cell network in Virginia.

Over the last several decades, pediatric care and medical advances have increased life expectancy for persons with sickle cell. However, health care delivery systems and public health initiatives supporting the optimal transfer from pediatric to adult care have not kept pace with the growing adult population. According to VDH data, the rate of emergency department (ED) visits for sickle cell disease in Virginia was highest among the 18-30 age group at 53.8 ED visits per 10,000 ED visits and 53.1 ED visits per 10,000 ED visits in 2018 and 2019 respectively.

Regulation 12VAC5-191-320 includes provisions for the Board of Health to work with comprehensive pediatric sickle cell centers to assure early entry into care within the first several months of life to prevent life threatening conditions. HB 907 authorized the Board of Health to expand its role to create an adult regional network, which will mirror the current Pediatric Comprehensive Sickle Cell Clinic Network. This regulatory action will include provisions for an adult comprehensive sickle cell clinic network to ensure better coordination in the transition from pediatric to adult sickle cell treatment.

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.

Board – Virginia Board of Health

ED – Emergency Department

HB – House Bill

SCD – Sickle Cell Disease

VDH – Virginia Department of Health or the Department

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 Board of Health approved these fast-track actions for 12 VAC 5 – 191 State Plan for Children with Special Health Care Needs on December 3, 2020.

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 Executive Order 14 (as amended, July 16, 2018), "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."

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

The mandate for this regulatory change is a result of HB 907 from the 2020 General Assembly session, which directs the Board to adopt regulations to implement an adult comprehensive sickle cell clinic network.

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.

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

Acts of Assembly 2020 Session, Chapter 503, Section 32.1-68 of the Code of Virginia requires the Board to adopt regulations to implement an adult comprehensive sickle cell clinic network.

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's intended to solve.

The purpose of this regulation is to be in compliance with the Code of Virginia and to implement an adult comprehensive sickle cell clinic network. Sickle cell disease (SCD) is a group of inherited, lifelong blood disorders that affects the red blood cells. In the United States, SCD disproportionately affects African Americans and those with a Hispanic background. Throughout the world, the disease affects those from the Middle East, Italy and Greece. Sickle cell affects every organ in the body. Complications include severe pain, stroke, acute chest syndrome, organ damage, and in some cases premature death. Increased sickle cell-related mortality has been shown in 18-30 year olds, with the highest rate of acute care encounters and re-hospitalizations in this age group compared to the older group of patients who would be expected to have increased illness and complications due to advancing age. According to VDH data, the rate of emergency department (ED) visits for sickle cell disease in Virginia was highest among the 18-30 age group at 53.8 ED visits per 10,000 ED visits and 53.1 ED visits per 10,000 ED visits in 2018 and 2019 respectively.

This regulatory change is essential to protect the health, safety and welfare of Virginians with sickle cell disease. There is a need to improve the coordination of care and transition of young adults with sickle cell from pediatric to adult medical care. Virginia has only one comprehensive adult sickle cell center, which is located at Virginia Commonwealth University. Barriers to a successful transition include: lack of comprehensive care programs for adults; lack of adult providers with skills and/or interest in caring for people with sickle cell, insurance coverage, and poor communication and follow-up between pediatric and adult providers.

The short-term goal of this regulatory change is the establishment of an adult comprehensive sickle cell clinic network. The long-term goal is a reduction in the rate of ED visits for adults with sickle cell in the 18-30 age group and an increase in the number of adults who continue into specialty care and establish a medical home with a specialty care provider.

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 purpose of the regulation is to amend one section and add two new sections to 12VAC5-191, State Plan for the Children with Special Health Care Needs Program.

- 12VAC5-191-40 is amended to include language that describes the adult sickle cell population.

- 12VAC5-191-330 is added to provide language that describes the Adult Comprehensive Sickle Cell Network.

- 12VAC5-191-340 is added to provide language that describes the scope of the Adult Comprehensive Sickle Cell Network.

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 of the proposed regulatory action to the public is that implementing an adult comprehensive sickle cell clinic network will establish the ability for the adult regional network to work with the pediatric network to ensure successful transition of persons with sickle cell disease. The intended result is continuity of services and treatment for this population of the public. There is no known disadvantage to the public associated with this regulatory change.

A primary advantage of the proposed regulatory action to the Commonwealth is that the action aligns with the recommendation from the American Society of Hematology to improve the pediatric to adult transition by ensuring qualified physicians in adult care are available to treat sickle cell disease. The primary disadvantage to the Commonwealth is the resulting cost of establishing and maintaining an adult regional network. Federal funding for sickle cell centers ended in 2008, and third party reimbursement for clinical services is generally low, requiring existing SCD comprehensive centers to rely on institutional support. The General Assembly approved funding in the amount of $305k to support implementation of the Adult Comprehensive Sickle Cell Clinic Network.

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 requirements more restrictive than applicable federal requirements.

Agencies, Localities, and Other Entities Particularly Affected

Identify any other state agencies, localities, or other entities particularly affected by the regulatory change. "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

No other state agencies will be particularly affected.

Localities Particularly Affected

No localities will be particularly affected.

Other Entities Particularly Affected

Individuals who are living with sickle cell disease and health care systems and providers that deliver health care services to those individuals will be particularly affected.

Economic Impact

Pursuant to § 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 change versus the status quo.

Impact on State Agencies

<table>
<tr><td>For your agency: 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</td><td>The regulatory change will provide $305,000 in general funds to VDH. Expenditures to support the Adult Comprehensive Sickle Cell Clinic Network will be ongoing. Existing VDH staff resources will be used to administer the Adult Comprehensive Sickle Cell Clinic Network. Projected costs of $305,000 for implementation are based on costs of the existing Pediatric Comprehensive Sickle Cell Clinic Network. The cost allocation for the pediatric network is below:

<table><tr><td>Region</td><td>Salaries/Fringe Benefits</td><td>Other Budgeted Costs</td><td>Total</td></tr><tr><td>Central</td><td>$80,000</td><td>$5,000</td><td>$85,000</td></tr><tr><td>Blue Ridge/SWVA</td><td>$47,500</td><td>$2,500</td><td>$50,000</td></tr><tr><td>Northern</td><td>$80,000</td><td>$5,000</td><td>$85,000</td></tr><tr><td>Hampton Roads</td><td>$80,000</td><td>$5,000</td><td>$85,000</td></tr><tr><td>Total</td><td>$287,500</td><td>$17,500</td><td>$305,000</td></tr></table></td></tr>
<tr><td>For other state agencies: projected costs, savings, fees or revenues resulting from the regulatory change, including a delineation of one-time versus on-going expenditures.</td><td>N/A</td></tr>
<tr><td>For all agencies: Benefits the regulatory change is designed to produce.</td><td>This regulatory change is intended to improve the care of sickle cell patients through successful transfer of care from pediatric to adult providers. Improved care coordination within the clinic network can potentially decrease emergency room visits, hospitalizations and</td></tr>
</table>

	readmission rates, which may also reduce Medicaid costs.

Impact on Localities

Projected costs, savings, fees or revenues resulting from the regulatory change.	N/A
Benefits the regulatory change is designed to produce.	N/A

Impact on Other Entities

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.	Individuals who are living with sickle cell disease are likely to be impacted. Health care systems and providers that deliver health care services to individuals living with sickle cell disease will be impacted by this regulatory 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.	It is estimated that there are 4,909 individuals living with sickle cell disease in Virginia. Virginia currently licenses over 70 acute care general hospitals. Virginia has 262.4 doctors per 100,000 people.
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.	Salary costs alone would be close to $1.8 million. Once fringe benefits are added, the cost would be close to $2.5 million (based on average fringe rate of 37.7%, Bureau of Labor Statistics, https://www.bls.gov/news.release/pdf/ecec.pdf). The chart below documents the potential costs to fully staff and fund four regional centers. Resources would support the provision of care for the estimated 4,909 individuals living in Virginia with SCD (estimate calculated using information from the CDC and population figures for the state of Virginia).

Staff	Average Salary	Fringe Rate	# FTE's	Total
Hematologist	$192,340	37.7%	4	$1,059,408.70
Nurse Practitioner	$111,141	37.7%	4	$612,164.60
Nurse	$75,429	37.7%	4	$415,462.92
Social Worker	$69,872	37.7%	4	$384,854.97
All costs				$2,471,891.10

**Average salaries for adult hematologists, specialty care nurse practitioners, specialty care nurses, and licensed clinical social workers was obtained from salary.com and glassdoor.com.*

	At an estimated total annual cost of $20,000/year/individual (American Society of Hematology), it is estimated that care for this number of people would exceed $98 million annually.
Benefits the regulatory change is designed to produce.	This regulatory change is intended to improve the care of sickle cell patients through successful transfer of care from pediatric to adult providers. Improved care coordination within the clinic network can potentially decrease emergency room visits, hospitalizations and readmission rates. Health care system costs may potentially decrease as a result of this regulatory change.

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.

No alternative to this regulatory action was considered, as the Code of Virginia addresses the need for regulations pertaining to the implementation of an adult comprehensive sickle cell clinic network.

Regulatory Flexibility Analysis

Pursuant to § 2.2-4007.1B 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.

§32.1-68 granted the Board of Health authority to expand its role to create an adult regional network that will mirror the current Pediatric Comprehensive Sickle Cell Clinic Network. VDH used 12VAC5-191-320, Scope and content of the Pediatric Comprehensive Sickle Cell Clinic Network, as the model regulation to promulgate regulations for the Adult Comprehensive Sickle Cell Clinic Network. VDH staff convened a stakeholder workgroup meeting to review and consider this regulatory change. Stakeholder workgroup representation included pediatric and adult sickle cell clinic providers, sickle cell community based organizations, individuals with sickle cell disease, caregivers of children with sickle cell disease and VDH staff. There are no other applicable regulations to consolidate which impact the implementation of an Adult Comprehensive Sickle Cell Clinic Network. Small businesses may not be exempted as a category because services for adults living with sickle cell must be managed equitably by their providers, regardless of business size, to assure optimal outcomes. There are no viable alternatives to the proposed regulatory action to achieve the necessary regulatory changes.

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.

As required by § 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 Robin Buskey, P.O. Box 2448, Richmond, VA 23218, 804-864-7652, and robin.buskey@vdh.virginia.gov. 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
12VAC5-191-40		Section 32.1-68 of the Code of Virginia requires the Board to adopt regulations to implement an adult comprehensive sickle cell clinic network. Subsection C includes a list of six existing networks and	Amends language to subsection C to include an additional network. VDH has proposed adding the following language: "7. Adult Comprehensive Sickle Cell Clinic Network." The rationale for this change is to expand the list of networks to include the Adult Sickle Cell Clinic Network pursuant

		services of the Children with Special Health Care Needs Program.	to the statutory requirement. Adding the Adult Comprehensive Sickle Cell Clinic Network to Chapter 191 aligns with the inclusion of the Virginia Bleeding Disorders Program (12VAC5-191-220), which also targets the adult population. The likely impact of this change will be increased coordinated care among providers to adults living with living with sickle cell.
		Subsection D includes language that describes the target population for the networks and services described in subsection C.	Amends language to subsection D. VDH has proposed adding the following language stating, "and the Adult Comprehensive Sickle Cell Clinic Network serves individuals age 18 and older." The addition of this language provides an adequate description of the intended target population for the Adult Comprehensive Sickle Cell Clinic Network. The likely impact of this change will be increased coordinated care among providers to adults living with sickle cell disease.
	12VAC5-191-330		Creation of a new section for the existing regulatory chapter. VDH has proposed regulatory language to provide a description of the Adult Comprehensive Sickle Cell Clinic Network, The likely impact of this section will be clarity and distinction between the Adult Comprehensive Sickle Cell Clinic Network and the Pediatric Comprehensive Sickle Cell Clinic Network to members of the public when reading the amended regulatory chapter.
	12VAC5-191-340		Creation of a new section for the existing regulatory chapter. VDH has proposed regulatory language that describes the mission, scope of services, eligibility criteria and goals of the Adult Comprehensive Sickle Cell Clinic Network, The regulatory language was modeled after 12VAC5-191-320. The likely impact of this section will be clarity for members of the public when reading the amended regulatory chapter.