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January 7, 2026

MEMORANDUM

TO: The Honorable Glenn Youngkin
Governor of Virginia

The Honorable Don Scott
Speaker of the House, Virginia House of Delegates

The Honorable L. Louise Lucas
President pro tempore, Senate of Virginia

FROM: Karen Shelton, MD
State Health Commissioner, Virginia Department of Health

SUBJECT: 2025 Report to the General Assembly on the Sickle Cell Disease Registry

This report is submitted in compliance with the Virginia Acts of the Assembly – § 32.1-73.27. Annual report; sickle cell disease registry, which states:

> *The Commissioner shall submit to the Governor and the General Assembly, by November 1 of each year, a report of the information obtained under this article.*

Should you have any questions or need additional information, please feel free to contact me at (804) 864-7002.

KS/KB
Enclosure

Pc: The Honorable Janet Kelly, Secretary of Health and Human Resources

STATEWIDE SICKLE CELL DISEASE REGISTRY

REPORT TO THE GOVERNOR AND THE GENERAL ASSEMBLY

2025

VIRGINIA DEPARTMENT OF HEALTH

PREFACE

In 2024, the General Assembly amended the Code of Virginia by adding § 32.1-73.22 to § 32.1-73.27, which directed the State Health Commissioner at the Virginia Department of Health (VDH) to establish and maintain a Statewide Sickle Cell Disease Registry. The Code requires that VDH submit a report of information obtained under these Code sections to the Governor and General Assembly by November 1 of each year.

REPORT CONTRIBUTORS

Virginia Department of Health

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EXECUTIVE SUMMARY

Sickle cell disease (SCD) is a group of inherited blood disorders that affect the shape and function of red blood cells. The Centers for Disease Control (CDC) estimates that there are approximately 100,000 people in America living with SCD (CDC, 2024). The number of people living with SCD in Virginia is currently unknown. In 2024, the General Assembly enacted Chapter 437 of the 2024 Acts of Assembly. This amended the Code of Virginia to add § 32.1-73.22 through § 32.1-73.27, which directs the State Health Commissioner at the Virginia Department of Health (VDH) to establish and maintain a Statewide Sickle Cell Disease Registry. The Code requires that VDH submit a report of information obtained under these Code sections to the Governor and General Assembly by November 1 of each year. This report seeks to fulfill that mandate for 2025.

Since the time of the last report, VDH has made significant progress towards establishing the registry. VDH staff finalized the plan for the design of the registry, hired additional staff to support the registry, developed the registry platform, and tested the registry platform with key partners who will use the platform to report data. Additional details on these activities and a summary of existing data on SCD in the Commonwealth are included in this report.

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INTRODUCTION

REGISTRY MANDATE

The Code of Virginia §§ 32.1-73.22 to 32.1-73.27 directs the State Health Commissioner at the Virginia Department of Health (VDH) to establish and maintain a Statewide Sickle Cell Disease Registry (SSCD Registry). The Code outlines who should report sickle cell disease (SCD) diagnoses to VDH, what information should be collected, what confidentiality measures should be in place, and the penalties for unauthorized use of registry information. The Code requires providers to notify patients that they are reporting their SCD diagnosis to the registry, allows patients to opt out of having their data reported to the registry, and allows patients to self-report their diagnosis to the registry. Additionally, the Code gives VDH the authority to promulgate regulations for data elements collected through the registry and for on-site data collection. Finally, the Code requires that VDH submit a report of information obtained under §§ 32.1-73.22 through 73.27 to the Governor and General Assembly by November 1 of each year.

See Appendix A for the full text of the legislation. The legislation went into effect on July 1, 2024.

REGISTRY ACTIVITIES

Since the time of the last report, VDH staff have continued to make progress towards establishing and implementing the SSCD Registry. VDH staff also began analyzing existing data on SCD in the Commonwealth. Progress over the past year includes:

- Finalized a design plan for the registry. The design plan includes information on the purpose of the registry; allowable uses, confidentiality, and safeguards; data elements to be collected; registry infrastructure and staffing; provider reporting process; notification and opt-out requirements for patients; patient self-reporting process; implementation rollout phases; regulatory considerations; and more.
- Developed the registry platform – the data infrastructure and data collection tool – in REDCap. The collection tool includes two forms: one for patients to self-report and one for providers to report.
- Hired a Sickle Cell Epidemiologist. The Epidemiologist helped set up the registry platform in REDCap and will manage ongoing data collection and data analysis for the registry. This Epidemiologist will also provide ongoing technical assistance to providers reporting sickle cell data.
- Met with health care providers who partner with VDH on sickle cell disease programs to collect feedback from them on the design of the registry and the REDCap database/form.
- Conducted beta testing of the registry with providers to test reporting data and ensure the registry data collection tool functions smoothly and accurately.
- Drafted materials for providers to share with patients about the SSCD Registry.

REPORT OUTLINE

The remainder of this report will provide background information on SCD and data that is available in the Commonwealth. It will also describe the progress of collecting information under the Code mandate, including activities VDH undertook this year to complete registry development. It will provide a high-level outline of the next steps that VDH will take to establish the registry and begin collecting data.

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BACKGROUND

Sickle cell disease (SCD) is a term used to describe a group of inherited blood disorders. SCD affects the shape and function of red blood cells. It is one of the most common genetic disorders in the United States, primarily affecting African Americans, and is also found in people from South and Central America, the Middle East, Italy, and Greece (VDH, 2017). People who have SCD have inherited two abnormal genes, with at least one being a sickle "S" gene.

Hemoglobin "S" gene changes the shape of red blood cells into a sickle shape. Sickle cells are hard and sticky, making it difficult to travel through small blood vessels (VDH, 2017). The disease can affect every organ system in the body and may cause pain that, at times, is excruciating.

INFORMATION OBTAINED (DATA COLLECTED)

The legislation directing the Virginia Department of Health (VDH) to establish the SSCD Registry went into effect in July 2024. Since then, VDH has established the registry infrastructure and data collection tool, and has beta tested that tool with VDH's sickle cell network partners. VDH will officially begin collecting data through the registry during the last quarter of 2025. During this first phase of data collection, VDH will require adult and pediatric sickle cell network providers that VDH partners with to report data on individuals with sickle cell disease through the registry. By 2026, VDH will then expand rollout of the registry to require all hospitals and private providers to report as well. Given this, there is no information obtained (data) yet to report under Article 22 of Chapter 2 of Title 32.1 this year.

However, as described below, VDH has some existing data on sickle cell disease in the Commonwealth. This primarily comes from VDH's newborn screening data and data provided from VDH's network of adult and pediatric sickle cell providers.

From 2012 to 2024, an average of 66 babies were born in Virginia each year with SCD, as identified by the Newborn Screening Blood Spot Program. Data about newborns born in Virginia who are confirmed with SCD can be found at: https://www.vdh.virginia.gov/sickle-cell-programs/sickle-cell-data-collection-program/sickle-cell-data-collection-scdc-newborn-screening-data/.

VDH has partnered with pediatric sickle cell treatment centers for many years, and VDH received state general funds to create an adult sickle cell network in 2021. In Q4 of SFY 2024 (April – June 2024), Virginia's pediatric and adult comprehensive sickle cell clinic network partners were serving approximately 2,000 people living with SCD, meaning 2,000 people were patients of the centers and receiving some kind of service from them (Table 1). More specifically, these partners reported providing services to 1,131 pediatric patients and 846 adult patients with SCD as of June 2024. These findings highlight the ongoing burden of SCD across the state, and the need for coordinated care and support services.

Table 1: Number of Individuals Registered to Receive Services by Pediatric and Adult Sickle Cell Center Partners (as of Q4 SFY 2024)

Virginia Sickle Cell/ Hemoglobinopathy Treatment Centers	Patients Registered to Receive Services in Q4 SFY 2024
Pediatric Sickle Cell Centers	
Children's Hospital of the King's Daughters	441
Pediatric Specialists of Virginia	315
Children's Hospital at VCU Richmond	313
University of Virginia Medical Center	62
Carilion Clinic Children's Hospital	Newly executed
Adult Sickle Cell Centers	
Virginia Commonwealth University	563
Inova Health Care Services	153
Carilion Medical Center	66
University of Virginia Health Benign Hematology	64
Eastern Virginia Medical School	Newly executed

Comparisons of the service levels above should be made with caution due to differences between each center. The pediatric sickle cell centers have been in existence for several decades, are well established, and receive direct referrals as required by the Virginia Administrative Code, via the Newborn Screening Bloodspot program. The first three centers (Children's Hospital of the King's Daughters, Pediatric Specialists of Virginia, and Children's Hospital at VCU Richmond) have larger numbers, considering they are located in larger population centers for patients living with SCD. The adult network has been in existence for less than three years and VDH's partners are still building their clinics, with the exception of VCU which has been in existence for many years as the only consistent provider of adult sickle cell care. Two new centers (Carilion Clinic Children's Hospital and Eastern Virginia Medical School) have been added under newly executed contracts. Data for these centers is not available yet.

Once launched, VDH plans to use the registry= to assist in determining the total number of people living in Virginia with SCD and to understand disease burden.

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SICKLE CELL DISEASE REGISTRY IMPLEMENTATION

Data collected from newborn screenings and the adult and pediatric sickle cell partners, provides a snapshot of the prevalence of SCD and the experience of those living with SCD in the Commonwealth. However, this data is not comprehensive and likely does not accurately capture the incidence of sickle cell disease statewide. Implementing a robust state-wide SCD registry and case estimation system will aid in data-driven decision-making, strengthening care infrastructure, and improving health outcomes for individuals with sickle cell disease.

PROGRESS: AUGUST 2024-2025

From August 2024 to August 2025, VDH made the following progress towards establishing the sickle cell disease registry, including both technical and organizational milestones:

1) Finalizing a design plan for the registry. The design plan includes information on the purpose of the registry; allowable uses, confidentiality, and safeguards; data elements to be collected; registry infrastructure and staffing; provider reporting process; notification and opt-out requirements for patients; patient self-reporting process; implementation rollout phases; regulatory considerations; and more.
2) Developing the registry data infrastructure, specifically REDCap as a database and data collection tool. The REDCap database design process and registry building included:
    - Monthly staff meetings to define REDCap data elements, ensuring their Health Insurance Portability and Accountability Act (HIPAA) compliance and adherence to the Code of Virginia.
    - Validating the REDCap data elements with clinical partners and incorporating the necessary changes to build a final REDCap database.
    - Creating a detailed data dictionary, and workflow simulations to test user case scenarios.
    - Documenting the registry data elements, providing rationale for inclusion of each element, and beginning to outline data elements proposed for future inclusion pending regulatory approval.
    - Developing two forms for entering information into the REDCap database – one for the medical providers to enter information about patients with sickle cell disease, and one for patients with sickle cell disease to self-report their information directly.
    - Beta testing the REDCap registry with designated sickle cell centers, refining the interface and user experience.
    - Finalizing a robust, user-friendly, fully operational REDCap database and registry platform.
3) Hiring a Sickle Cell Epidemiologist, who helped set up the registry data infrastructure and data collection tool in REDCap. The Epidemiologist will manage ongoing data collection and data analysis for the registry. This Epidemiologist will also provide ongoing technical assistance to providers reporting sickle cell data.
    - The Sickle Cell Epidemiologist joined the VDH staff workgroup that has been overseeing the development and implementation of the registry. This workgroup includes the following staff at VDH within the Office of Family Health Services (OFHS):

   i. OFHS Office Director
   ii. Director of the Division of Child and Family Health
   iii. Director of the Division of Population Health Data
   iv. Staff from the Children and Youth with Special Healthcare Needs (CYSHCN) unit (charged with managing the registry)
   v. The Sickle Cell Epidemiologist
   vi. The Infant and Child Health Epidemiologist
   vii. Policy Analyst
4) Meeting with health care providers who partner with VDH on sickle cell disease programs to collect feedback from them on the design of the registry and the registry collection tool (REDCap).
5) Conducting beta testing of the registry with providers to test reporting data and ensure the registry data collection tool functions smoothly and accurately.
6) Creating materials for providers to share with patients who have questions about the registry or are interested in opting out.

NEXT STEPS

Over the next year, VDH anticipates taking the following steps to continue implementation of the registry:

- Develop and distribute communication materials and updates for providers and patients about the SSCD Registry.
- By Q4 2025, begin collecting data/mandating reporting from VDH sickle cell network partners.
- By 2026, roll out the registry and reporting requirements to all hospitals and private providers (in that order) who care for people living with sickle cell disease.
- Provide technical assistance and trainings to providers to ensure accurate and timely reporting through REDCap.
- Establish ongoing data monitoring and validation mechanisms.
- Begin analysis and reporting based on the registry data.
- Draft regulations to guide the future scope and governance of the registry.

REFERENCES

Centers for Disease Control and Prevention. (2024, August 26). *Sickle Cell Disease.* *https://www.cdc.gov/sickle-cell/scdc/index.html#:~:text=The%20Centers%20for%20Disease%20Control%20and*

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Virginia Department of Health. (2022, December 12). *Sickle Cell Data Collection (SCDC) Newborn Screening Data.* *https://www.vdh.virginia.gov/sickle-cell-programs/sickle-cell- data-collection-program/sickle-cell-data-collection-scdc-newborn-screening-data/*

APPENDIX A – CHAPTER 437 OF THE 2024 ACTS OF ASSEMBLY

Be it enacted by the General Assembly of Virginia:

1. That the Code of Virginia is amended by adding in Chapter 2 of Title 32.1 an article numbered 22, consisting of a section numbered, § 32.1-73.22-§ 32.1-73.27 as follows:

Article 22. Statewide Sickle Cell Disease Registry.

§ 32.1-73.22. Information from hospitals, clinics, certain laboratories, and physicians supplied to Commissioner; statewide sickle cell disease registry.

Each hospital, clinic, and independent pathology laboratory shall make available to the Commissioner or his agents information on patients having sickle cell disease. A physician shall report information on patients having sickle cell disease unless he has determined that a hospital, clinic, or in-state pathology laboratory has reported the information. Such information shall include the name, address, sex, race, diagnosis, trait status, newborn screening data, and any other pertinent identifying information regarding each such patient. Each hospital, clinic, independent pathology laboratory, or physician shall provide other available clinical information as defined by the Board.

From such information the Commissioner shall establish and maintain a statewide sickle cell disease registry. The purpose of the statewide sickle cell disease registry shall include:

Determining means of improving the diagnosis and treatment of sickle cell disease patients.

Determining the need for and means of providing better long-term, follow-up care to sickle cell disease patients.

Conducting epidemiological analyses of the incidence, prevalence, survival, and risk factors associated with the occurrence of sickle cell disease in Virginia.

Improving rehabilitative programs for sickle cell disease patients.

Assisting in the training of hospital personnel.

Determining other needs of sickle cell disease patients and health personnel. 2024, c. 437.

§ 32.1-73.23. Collection of sickle cell disease case information by the Commissioner.

Using such funds as may be appropriated therefor, the Commissioner or his designee may perform on-site data collection of the records of patients having sickle cell disease at those consenting hospitals, clinics, independent pathology laboratories, and physician offices required to report information on such patients pursuant to the reporting requirements of § 32.1-73.22 in order to ensure the completeness and accuracy of the statewide sickle cell disease registry.

The selection criteria for determining which consenting hospitals, clinics, independent pathology laboratories, and physician offices may be subject to on-site data collection under the provisions of this section shall include (i) the expected annual number of sickle cell disease case reports from each such facility, (ii) the historical completeness and accuracy of reporting rates of each facility under consideration, and (iii) whether the facility maintains its own sickle cell disease registry.

The Board shall promulgate regulations necessary to implement the provisions of this section. 2024, c. 437.

§ 32.1-73.24. Confidential nature of information supplied; publication; reciprocal data- sharing agreements.

The Commissioner and all persons to whom information is submitted in accordance with § 32.1-73.22 shall keep such information confidential. Except as authorized by the Commissioner in accordance with the provisions of § 32.1-41, no release of any such information shall be made except in the form of statistical or other studies that do not identify individual cases.

The Commissioner may enter into reciprocal data-sharing agreements with other sickle cell disease registries for the exchange of information. Upon the provision of satisfactory assurances for the preservation of the confidentiality of such information, patient-identifying information may be exchanged with other sickle cell disease registries that have entered into reciprocal data-sharing agreements with the Commissioner.

2024, c. 437.

§ 32.1-73.25. Penalties for unauthorized use of statewide sickle cell disease registry.

In addition to the remedies provided in § 32.1-27, any person who uses, discloses, or releases data maintained in the statewide sickle cell disease registry in violation of § 32.1-73.24 shall be subject, in the discretion of the court, to a civil penalty not to exceed $25,000 for each violation, which shall be paid to the general fund.

2024, c. 437.

§ 32.1-73.26. Notification of sickle cell disease patients of statewide sickle cell disease registry reporting.

Any physician diagnosing sickle cell disease shall, at such time and in such manner as considered appropriate by such physician, notify each patient whose name and record abstract is required to be reported to the statewide sickle cell disease registry pursuant to § 32.1-73.22 that personal identifying information about him has been included in the registry as required by law. Any physician required to so notify a patient that personal identifying information about him has been included in the sickle cell disease registry may, when, in the opinion of the physician, such notice would be injurious to the patient's health or well-being, provide the required notice to the patient's authorized representative or next of kin in lieu of notifying the patient.

Upon request to the statewide sickle cell disease registry, the patient whose personal identifying information has been submitted to such registry shall have a right to know the identity of the reporter of his information to such registry. A patient diagnosed with sickle cell disease may self-report information to the statewide sickle cell disease registry. A patient diagnosed with sickle cell disease shall have the right to opt out of having his data reported to the statewide sickle cell disease registry.

2024, c. 437.

§ 32.1-73.27. Annual report; sickle cell disease registry.

The Commissioner shall submit to the Governor and the General Assembly, by November 1 of each year, a report of the information obtained under this article.

2024, c. 437.

APPENDIX B – ACRONYMS AND ABBREVIATIONS

This is a listing of the acronyms and abbreviations appearing throughout the report and its appendices.

DCFH – Division of Child and Family Health

DPHD – Division of Population Health Data

CYSHCN – Children and Youth with Special Health Care Needs

OFHS – Office of Family Health Services

OIM – Office of Information Management

SCD – Sickle Cell Disease

SSCD Registry – Statewide Sickle Cell Disease Registry

VDH – Virginia Department of Health