COMMONWEALTH of VIRGINIA

Department of Health

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December 23, 2024

MEMORANDUM

TO: The Honorable Glenn Youngkin
Governor of Virginia

The Honorable L. Louise Lucas
President Pro Tempore, Senate of Virginia

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

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

SUBJECT: 2024 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/AJ
Enclosure

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

STATEWIDE SICKLE CELL DISEASE REGISTRY

REPORT TO THE GOVERNOR AND THE GENERAL ASSEMBLY

2024

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

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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 2024.

Since § 32.1-73.22 through § 32.1-73.27 became effective on July 1, 2024, VDH has made progress towards establishing the registry. An internal team has been working to plan the design, development, and implementation of the registry. This included collecting information from other states who have such a registry and from relevant stakeholders, such as a local pediatric hematologist who maintains a registry of their pediatric patients in Northern Virginia, to inform the design of the registry.

INTRODUCTION

REPORT 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.

REGISTRY ACTIVITIES

In May 2024, VDH established an internal work group to plan the design and implementation of the SSCD Registry, in anticipation of the new legislation becoming effective in July 2024. Since May, the work group has met monthly and made progress towards establishing the registry. This included:

- Developing an internal implementation workplan for the registry.
- Developing an internal budget and staffing plan for the registry.
- Developing initial communications materials for the registry. This included publishing and distributing an update to stakeholders on the status of the registry and creating a distribution list for stakeholders to sign up to receive additional registry implementation updates from VDH.
- Collecting information from stakeholders to inform the design of the registry. This included having conversations with other states who have established their own registries and with providers in Virginia who will be impacted by the registry.
- Exploring potential mechanisms through which VDH could collect the registry data and identifying a proposed plan for registry infrastructure.
- Beginning the hiring process for a Sickle Cell Epidemiologist to support the registry.
- Drafting a registry design plan, which will be a living document that VDH intends to iterate on with stakeholders. The draft 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 data retention.

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 begin 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.

BACKGROUND

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)

Because the legislation directing VDH to establish the SSCD Registry just went into effect in July 2024, the agency is still in the process of designing and establishing the registry and there is no information obtained (data) to report under Article 22 of Chapter 2 of Title 32.1 this year. VDH anticipates it will have collected initial data to report by 2025, which will be included in next year's annual report to the Governor and General Assembly.

VDH does know that, in Virginia, approximately 75 babies are born each year with sickle cell disease who are detected through the newborn screening blood spot program (VDH, 2022). Data about newborns born in our state who screen positive for 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/. In addition, Virginia's pediatric and adult comprehensive sickle cell clinic networks serve approximately 1,800 people living with SCD. VDH plans to use the registry, once created, to assist in determining the total number of people living in Virginia with SCD and to understand disease burden.

PROGRESS TOWARDS IMPLEMENTATION OF THE STATEWIDE SICKLE CELL DISEASE REGISTRY

Over the past few months, VDH staff have made progress towards establishing the registry. Key progress included:

1. **Forming an internal work group to design and implement the registry.** VDH formed an internal work group of staff charged with the development and implementation of the sickle cell registry. Staff are located in the VDH Office of Family Health Services (OFHS). The group consists of the Director of the Division of Child and Family Health (DCFH), internal staff of the Children and Youth with Special Healthcare Needs (CYSHCN) unit (charged with managing the registry), the Policy Analyst for the OFHS, the Director of the Division of Population Health Data, and the OFHS Director. Staff

have been meeting at least once a month to touch base on progress towards implementation, workshop materials, address any issues that have arisen, and plan next steps.

2. **Developing an internal implementation plan, budget, and staffing plan to ensure efficient establishment of the registry.** The internal implementation plan outlines high-level activities that VDH staff intend to conduct to implement the registry. The budget is aligned with the allocation of General Funds in the SFY25-26 budget for this program, and includes funding for staffing, technical infrastructure, and materials/travel. The draft staffing plan for the registry includes three FTEs: a Sickle Cell Program Coordinator (responsible for registry oversight and strategy); a Sickle Cell Registry Program Specialist (responsible for day-to-day program operations and stakeholder engagement); and a Sickle Cell Epidemiologist (responsible for registry data collection, analysis, and technical assistance). While those positions are in recruit, the CYSHCN Program Director will manage the registry.

3. **Developing initial communications materials for the registry**. The first act of the internal work group was to publish a statement on VDH's website about the status of the registry (Appendix C). VDH also created a process online that allows interested parties to receive updates about the registry.

4. **Collecting information from stakeholders to inform the design of the registry.** VDH reached out to stakeholders in other states and in the Commonwealth to learn more about existing sickle cell disease registries and how they are designed/maintained. VDH consulted with stakeholders in South Carolina and Nevada who established and are currently overseeing statewide sickle cell registries. VDH also consulted with a physician partner in Northern Virginia who manages their own registry of patients, and with one of the major health systems in the state to understand what questions they already had about the registry.

5. **Exploring potential mechanisms through which VDH could collect the registry data and identifying a proposed plan for registry infrastructure.** The internal work group investigated potential platforms for collecting registry data from providers, including whether the registry could use any existing agency reporting mechanisms. The work group determined that given the unique requirements of the registry (such as the opt-out option for individuals) and existing partnerships with sickle cell service providers in the field, the best way to move forward would be to establish a reporting mechanism specific to the SSCD Registry. The team considered two primary options for collecting and storing registry data: 1) Using REDCap, a HIPAA-compliant secure web application for building and managing online surveys and databases (Vanderbilt University, 2024) and 2) Developing a new data collection and management system that would be housed at VDH. The work group consulted with the VDH Office of Information Management (OIM) and with internal and external stakeholders who have experience using REDCap to solicit feedback on these options. The work group determined from these conversations that while an in-house data collection and management system is likely the best long-term solution, developing and rendering this platform operational for data collection would take several years. The work group learned that other partners have successfully used

REDCap to collect information for sickle cell registries and other disease registries. VDH already has full access to REDCap and multiple OFHS programs use REDCap to collect and store information. Given this, the work group is proposing a two-part development of the registry infrastructure. First, the agency will begin to collect and store data for the SSCD Registry using REDCap. This will allow the agency to have the registry operable within a year, and therefore data will be available to the Commonwealth more expeditiously. Then, after the registry is fully operational in REDCap, VDH will explore establishing to a more permanent database housed at VDH.

6. **Beginning the hiring process for a Sickle Cell Epidemiologist to support the registry**. In order to have the staff needed to manage the registry, VDH has moved forward with the process of hiring an epidemiologist. This position will be responsible for creating the registry, beta testing the registry with clinical partners, producing data reports for the registry, and day-to-day management of all data related to the registry. The epidemiologist is a critical position and will be hired first. After the epidemiologist has been hired, VDH will hire a registry program specialist charged with the overall management of the registry. This will include, but is not limited to, visiting clinical partners to offer technical assistance; publishing of data reports with the epidemiologist; writing the annual report to the Governor and General Assembly; managing stakeholder communications, including meetings with stakeholders to discuss data; and working with staff to promulgate regulations. In addition to the staff mentioned above, VDH is working to backfill the state sickle cell coordinator position. This position was vacated in May of 2024 and will be responsible for managing registry staff. In the interim, the CYSHCN Director is managing the project.

7. **Drafting a registry design plan, which will be a living document that VDH intends to iterate on with stakeholders.** The design plan is still a work in progress. It 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 data retention.

NEXT STEPS

VDH anticipates that the registry will be created, tested, and ready for initial data entry by the end of calendar year 2025. VDH will be able to report on initial data collected through the registry in the next annual report to the Governor and General Assembly. Next steps for the agency to establish the SSCD Registry include:

- Soliciting input from stakeholders on the design of the registry and continuing to iterate on the design plan for the registry
- Continuing to hire positions to support the development and implementation of the registry, including the Sickle Cell Epidemiologist and the Sickle Cell Program Coordinator
- Setting up the REDCap database
- Rolling out and testing the REDCap database with providers
- Developing updates and communication materials for providers and patients
- Providing ongoing technical assistance and trainings to providers to ensure accurate and timely reporting
- As needed, drafting regulations to guide on site data collection and data elements collected through 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.

A. 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.

B. 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:

1. Determining means of improving the diagnosis and treatment of sickle cell disease patients.
2. Determining the need for and means of providing better long-term, follow-up care to sickle cell disease patients.
3. Conducting epidemiological analyses of the incidence, prevalence, survival, and risk factors associated with the occurrence of sickle cell disease in Virginia.
4. Improving rehabilitative programs for sickle cell disease patients.
5. Assisting in the training of hospital personnel.
6. 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.

A. 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.

B. 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.

C. 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.

A. 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.

B. 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.

A. 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.

B. 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.

CDC – Centers for Disease Prevention and Control

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

APPENDIX C – STATEWIDE SICKLE CELL DISEASE REGISTRY STATEMENT

Statewide Sickle Cell Disease Registry Statement

July 15, 2024

Background

On April 4, 2024, Governor Glenn Youngkin signed into law HB 252 which mandates the creation of a statewide registry for sickle cell disease, including the collection of disease case information. The law has been enacted as Chapter 437 of the 2024 Acts of Assembly.

The statewide registry of sickle cell patients will be maintained by the Virginia State Health Commissioner. The new law adds Sections 32.1-73.22 through 32.1-73.27 to the Code of Virginia. The law includes information about who shall report data to the registry, the purpose of the registry, parameters for the collection of the data, confidentiality of the registry data, penalties for unauthorized use of the registry data, and patient rights. The law specifically stipulates that patients with sickle cell disease may self-report and may opt out of having their data reported to the statewide sickle cell disease registry. Finally, the law requires the Board of Health to promulgate regulations pertaining to on-site data collection and requires the State Health Commissioner to submit an annual report on the status of the registry to the Governor and General Assembly.

Status Update

Per the Code, the Virginia Department of Health (VDH) is responsible for establishing and maintaining the statewide sickle cell registry. HB 252 became effective July 1, 2024.

As of July 1, VDH has begun engaging in work to design the registry and establish its infrastructure, pursuant to the Code. This includes identifying the processes through which data will be collected, selecting the data elements the agency will collect, and drafting regulations. VDH plans to seek stakeholder input on the design of the registry.

Once VDH has finalized the plans for the design of the registry, VDH will determine a timeline for each phase of implementation to communicate to stakeholders.

Given this, hospitals, clinics, laboratories, and physicians are not yet required to collect data on patients with sickle cell. VDH will keep stakeholders informed of updates related to the status of the registry, including when providers will be expected to begin collecting data and the guidelines for collection and reporting. VDH will provide informative materials and technical assistance to support providers in collecting this information at that time.

What This Means for Providers

Hospitals, clinics, laboratories, and physicians should wait for further outreach from VDH to begin collecting this data. If you are interested in staying updated on the agency's progress on the registry, you can fill out this form to join our outreach list.