Expanding Access to Sickle Cell Disease Treatment in Virginia

November 26, 2024

Study Purpose

- Describe state programs that identify and monitor sickle cell disease (SCD)
- Identify available data on individuals living with SCD
- Describe state funding to support education, monitoring and treatment of SCD
- Identify barriers to care for individuals living with SCD and recommend strategies to address these barriers

NOTE: JCHC Members approved a targeted study of SCD on June 11, 2024, based on House Joint Resolution 60 (Hayes) from the 2024 General Assembly session.

General Assembly directed DMAS and VDH to report annually on SCD

- House Bill 820 (Mundon King) directed DMAS to conduct an annual review of medication, treatments and services
- House Bill 252 (Cole) directed VDH to establish a statewide sickle cell registry
- JCHC staff maintained awareness of these efforts but did not further address them in the study to limit duplication of effort

DMAS = Department of Medical Assistance Services; VDH = Virginia Department of Health
NOTE: House Bills 820 and 252 were enacted during the 2024 Session of the General Assembly

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Overview of sickle cell disease (SCD)

Identifying and monitoring SCD in Virginia

Options for SCD treatment

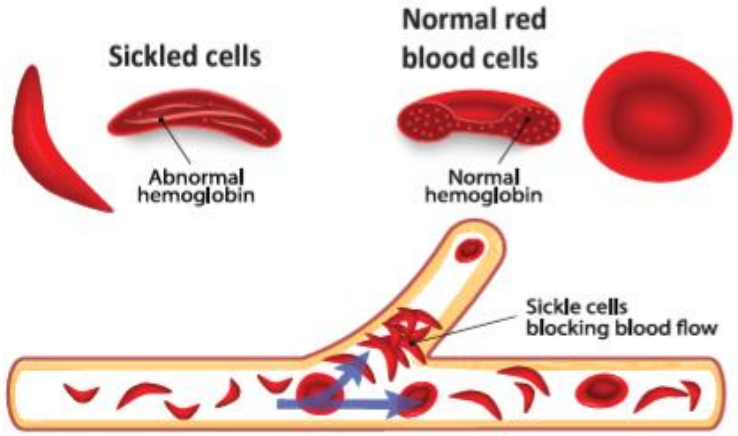
State programs to support individuals with SCD

Systemic and structural barriers to SCD care

Cost and insurance barriers to SCD care

Sickle cell disease is an inherited blood disorder that affects blood flow

- SCD refers to a group of inherited blood disorders that affect hemoglobin, a molecule that red blood cells need to carry oxygen
- Sickled cells cause blockages in blood vessels, inhibiting blood flow and leading to severe pain and medical complications



Sickle cell disease primarily impacts Black individuals

- More than 90 percent of individuals diagnosed with SCD in the United States are Black
- Approximately 1 in every 365 Black babies born in the United States is diagnosed with SCD
- Approximately 1 in every 13 Black babies born in the United States has SCT

SCT = sickle cell trait

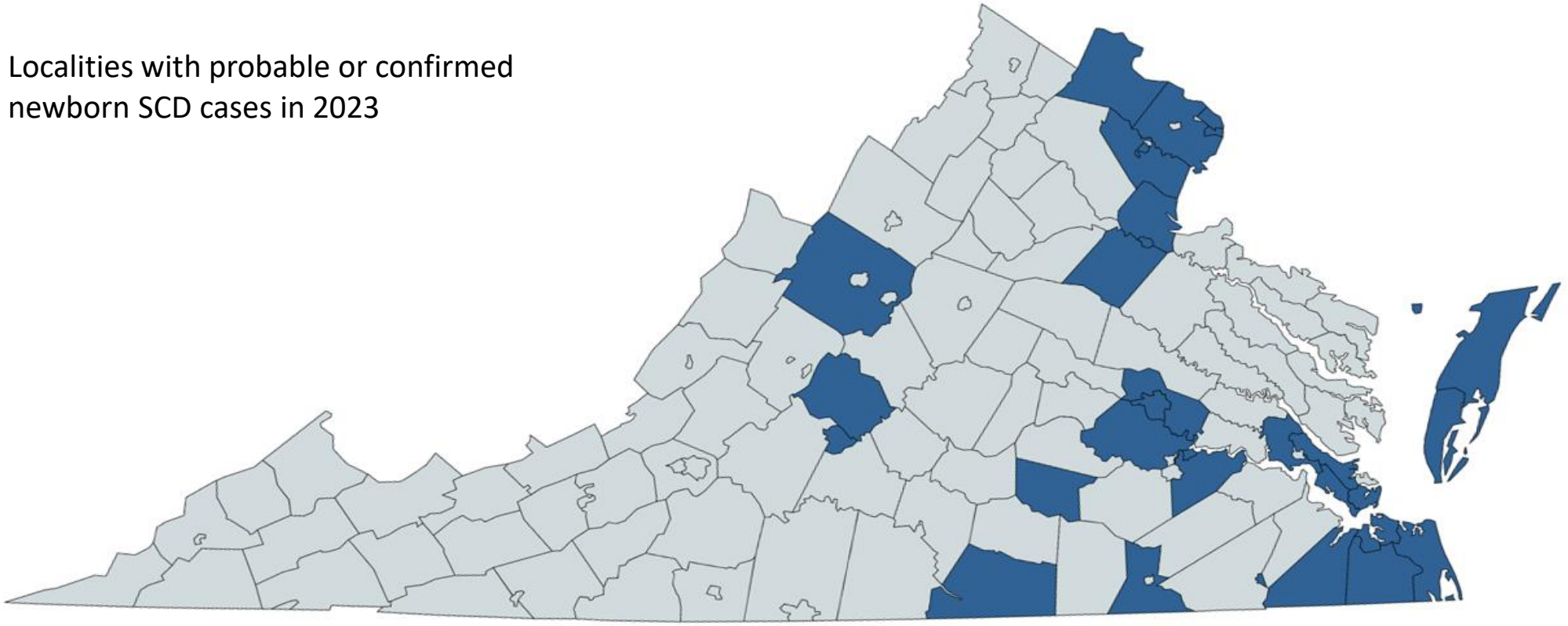
Information on number of individuals with sickle cell disease is limited

- Absent national and state level monitoring programs, exact number of individuals with SCD is not known
- CDC estimates:
  - Approximately 100,000 individuals with SCD nationally
  - Approximately 4,000 individuals with SCD in Virginia

CDC = Centers for Disease Control and Prevention

In 2023, Virginia reported 66 probable or confirmed newborn cases of SCD

Localities with probable or confirmed newborn SCD cases in 2023



SOURCE: JCHC analysis of Virginia Department of Health newborn screening data, 2024.
NOTE: Most localities had less than five confirmed cases, therefore exact case numbers are not reported.

SCD impacts all aspects of an individual's life

- Individuals with SCD must manage the physical, mental, and emotional toll of disease symptoms and pain
- SCD is expensive
  - Direct health care costs to patients and payers are high
  - Indirect costs include productivity loss and education loss

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Virginia newborn screening program identifies potential new cases of SCD

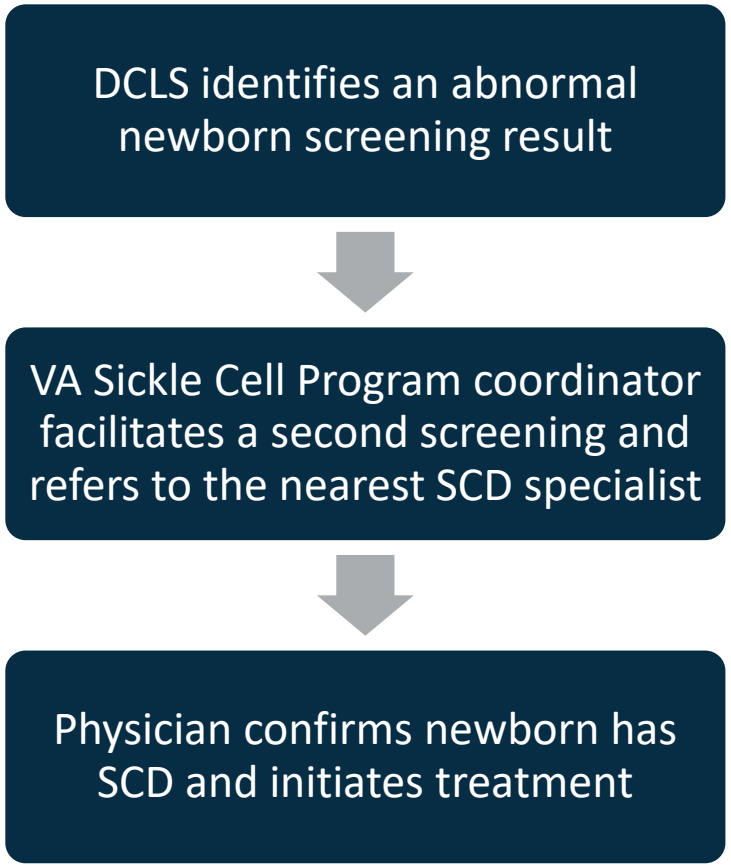
- Newborn screening (NBS) programs identify conditions that affect long-term health and survival
- Since 1989, Virginia's NBS program screens for the presence of abnormal hemoglobin through a blood sample; screening cannot confirm SCD
- All NBS blood samples are processed by the Division of Consolidated Laboratory Services (DCLS)

Virginia Sickle Cell Awareness Program facilitates diagnosis and linkage to care

The Virginia Sickle Cell Awareness Program is responsible for:

- **Facilitating diagnostic testing** and providing follow-up education to individuals and families with SCD
- **Facilitating entry to care** for individuals with SCD at the nearest SCD treatment center
- **Raising awareness of SCD** in the community

DCLS = Division of Consolidated Laboratory Services



Virginia encourages health care providers to offer sickle cell screening

- Individuals born before 1989 may not be aware of their SCD or SCT status
- House Bill 255 (Mundon King) encourages adult SCD or SCT screening and requires health care providers to offer education and counseling on results
- Adult SCD and SCT testing is voluntary, and reporting is not required

Virginia does not have a system to track adults or newborns confirmed with SCD

- House Bill 252 (Cole) directed VDH to develop a statewide SCD registry to monitor confirmed cases of SCD to support patient care and ongoing disease surveillance
  - The GA appropriated $405K in FY25 and FY26 for the SCD registry and required annual reports on information obtained by the registry
- Additional transparency on VDH implementation could ensure final product aligns with intended goals

GA = General Assembly, FY = fiscal year, VDH = Virginia Department of Health

Policy Option 1

JCHC could write a letter to request that VDH provide an update on the plan for and status of the SCD registry, including information about the types of data that will be collected, how the data will be used, and who will be able to access the data.

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SCD treatment focuses on preventing sickling, managing pain and other complications

SOURCE: JCHC analysis of peer-reviewed literature, 2024. See TABLE 1 on page 8 of full report for more information.

Appropriate pain management is a primary concern in SCD treatment

- Individuals with SCD experience acute and chronic pain
- Blockages caused by sickled cells cause pain and serious damage to organs – these episodes are called “pain crises”
- During pain crises, patients are most frequently managed with opioids

Stem cell transplants are the only curative therapy for SCD

- Stem cell transplantation is not recommended for everyone with SCD
  - The treatment is very risky and may lead to other complications
  - Patients and providers must weigh the potential benefits against the risks
- New gene therapies make stem cell transplantation more effective but cost and limited access may limit impact

SCD treatment can cause fertility issues

- SCD treatment guidelines do not address infertility that results from medical treatment (iatrogenic infertility)
- Individuals with SCD and their providers must weigh the benefits and risks of pursuing fertility preservation treatments

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The General Assembly appropriated $1.4M in FY25-26 to coordinate SCD care

Recipient	FY25-FY26 Funding
Statewide Sickle Cell Chapters of Virginia	$105,000
Pediatric Comprehensive Sickle Cell Clinic Network	$450,000
Adult Comprehensive Sickle Cell Clinic Network	$880,000
TOTAL	$1,435,000

NOTE: This table does not reflect General Assembly funding to VDH to develop a statewide SCD registry.

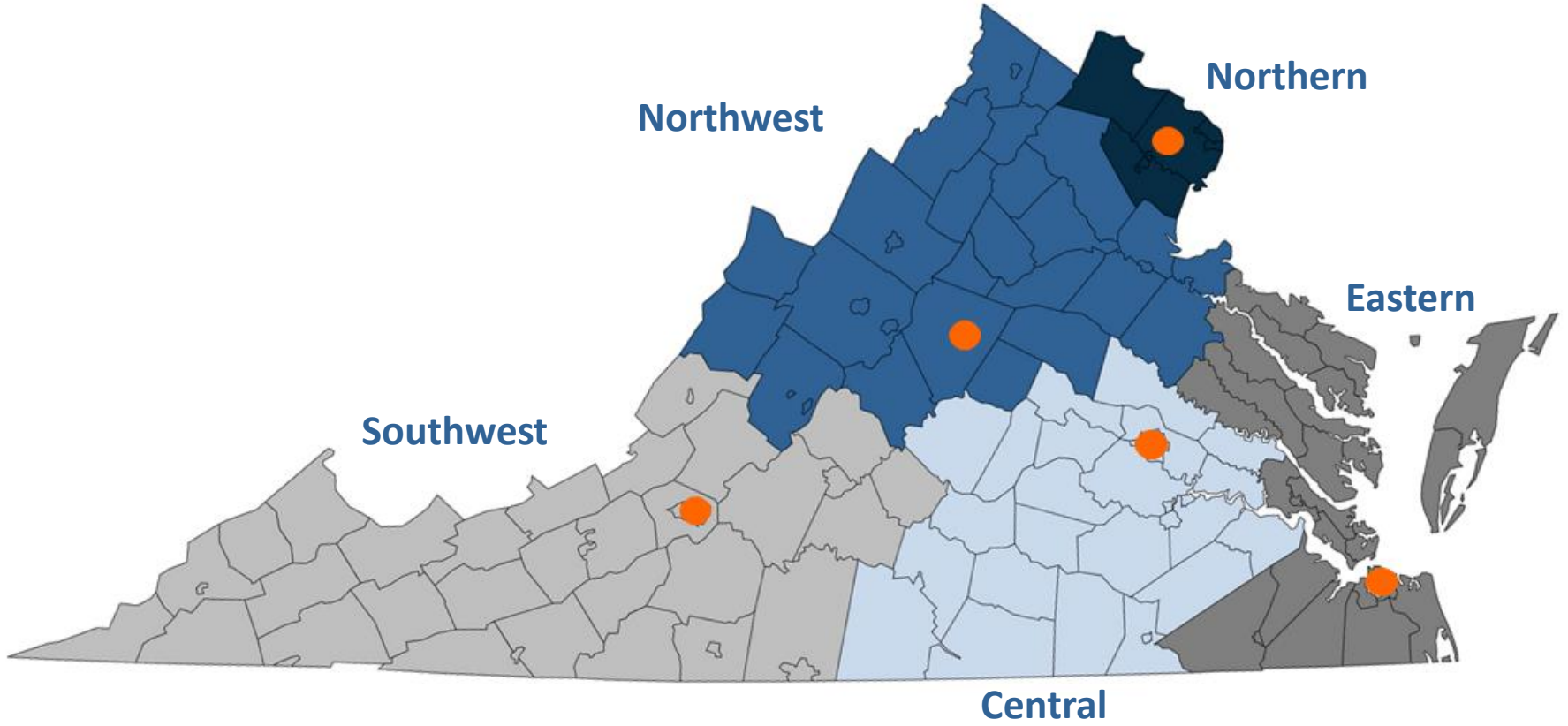
Regional community-based organizations receive $105K annually

- The Statewide Sickle Cell Chapters of Virginia (SSCCV) are a network of nine community-based organizations that support individuals living with SCD across Virginia
- State funding supports grants to organizations to provide:
  - Patient assistance
  - Education
  - Family-centered support

Pediatric and adult SCD treatment centers provide access to specialized care

- Treatment centers are the primary source of specialized SCD care in Virginia including:
  - Direct and clinical care services
  - Wraparound and support services
- Virginia's SCD treatment centers are embedded within larger hospital systems' hematology/oncology departments

Pediatric and adult SCD treatment centers exist in every health region



SOURCE: JCHC analysis of Virginia Sickle Cell Awareness Program document data, September 2024.

VDH contracts help fund wraparound services and supports for SCD patients

- VDH contracts with SCD treatment centers to participate in Pediatric and Adult Comprehensive Sickle Cell Clinic Networks
- SCD treatment centers participating in the Networks receive funds to help offset the costs of providing wraparound services:
  - Care coordination and case management
  - Counseling and education
  - Transition support from pediatric to adult care
- State funds do not cover the cost of treatment

Funding for Comprehensive Sickle Cell Clinic Networks has increased in recent years

	Pediatric Sickle Cell Network Funding	Adult Sickle Cell Network Funding	Total
FY 2021	$305,000	$305,000	**$610,000**
FY 2022	$305,000	$805,000	**$1,110,000**
FY 2023	$305,000	$805,000	**$1,110,000**
FY 2024	$305,000	$805,000	**$1,110,000**
FY 2025	$450,000	$880,000	**$1,330,000**

SOURCE: JCHC analysis of Virginia State Budget.

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Individuals living with SCD navigate systemic and structural barriers to care

- Lack of accessible, appropriate health care services
- Lack of information and education for health care providers
- Presence of stigma and unconscious bias

Treatment centers lack capacity to meet need for treatment services

- SCD patients have the best outcomes when they can access providers who are familiar with how to treat SCD
- In Virginia, the only access to specialized treatment is at comprehensive sickle cell treatment centers
- Lack of dedicated resources limits treatment centers' capacity to meet patients' need for treatment services
  - Shared clinical staff limit availability and reach of clinic services
  - Absent state funding, treatment centers must rely on affiliated health systems to provide resources to expand capacity

Treatment centers need additional capacity to support patients transitioning to adult care

- SCD patients are most vulnerable as they enter early adulthood
  - Emergency department visits for SCD are highest among 18–30-year-olds
- The Virginia Sickle Cell Awareness Program encourages strong relationships between Pediatric and Adult Comprehensive Sickle Cell Clinic Network participants
  - Treatment centers differ in the transition services available

Treatment centers do not have capacity to meet patients' psychosocial needs

- SCD takes an immense psychosocial toll
  - Stress and anxiety from ongoing, frequent pain
  - Missing experiences and milestones of peers
- Individuals with SCD have increased likelihood of developing a substance use disorder but no more than individuals with other chronic conditions
- Treatment centers cited difficulty finding mental health providers to serve their patients' needs

Adult comprehensive SCD treatment centers previously sought state funding

Position Type	Requested Position Title	Total Funding Requested
Clinical Staff for Direct Care Services	Advance Practice Providers (e.g., Physician Assistant)	$1,025,000
	Physicians (specializing in SCD, hematology, pain management)	$728,000
	Registered Nurse Coordinators/Physician for gene therapy	$285,000
	Registered Nurses for infusion/pain clinic	$560,000
	Total	**$2,598,000**
Staff for Mental Health and Care Transition Supports	Community Health Worker	$340,000
	Licensed Clinical Social Worker/Master's in Social Work	$517,000
	Nurse Navigator	$50,000
	Psychiatrist/Clinical Psychologist	$378,000
	Transition Patient Navigator	$276,000
	Total	**$1,561,000**

SOURCE: Sickle Cell Association of Virginia, 2024 budget amendment request for funding to support adult comprehensive SCD treatment centers.

General Assembly could provide funding to expand capacity at treatment centers

- Previous budget amendment does not include pediatric treatment centers
- Additional information may be necessary to understand the extent of unmet need and resources required to fill gaps

Policy Option 2

The JCHC could introduce a budget amendment to provide funds to VDH for a needs assessment to determine the extent of need for treatment, transition, and mental health and other psychosocial support services for patients at treatment centers and require VDH to develop a plan to address such need.

Transportation to treatment facilities is a major barrier for individuals with SCD

- Individuals with SCD who do not live near a sickle cell treatment facility must travel long distances to access appropriate care
  - Several stakeholders reported traveling more than two hours to their nearest treatment center
- Non-emergency medical transportation for Medicaid patients must be booked in advance and may not be available when a pain crisis arrives

Policy Option 3

The JCHC could introduce a budget amendment to provide funds to VDH for a needs assessment to determine the extent of the need for transportation services for patients at treatment centers and require VDH to develop a plan to address such need.

Providers' lack of knowledge about SCD interferes with timely treatment in the ED

- Emergency department providers are unfamiliar with caring for individuals with SCD
- Providers are uncomfortable prescribing the volume of opioids SCD patients typically need
- Unknown if SCD registry could help address this issue

Policy Option 4

The JCHC could introduce a Section 1 bill directing VDH to develop a plan to ensure health care providers in hospital emergency departments have access to information to confirm patients' sickle cell status and facilitate timely and appropriate access to care.

Stigma and bias about individuals with SCD can delay care

- Research shows bias can lead to delays in treatment for individuals with SCD and contribute to poorer outcomes
- Providers often perceive adults with SCD to have increased risk of substance abuse, making them hesitant to administer opioids for pain treatment
- Patients with SCD seeking treatment for pain crises in hospital EDs experience significant delays in care

Policy Option 5

The JCHC could introduce legislation directing the Boards of Medicine and Nursing to require unconscious bias and cultural competency training as part of the continuing education and continuing competency requirements for renewal of licensure.

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Addressing treatment costs and insurance barriers could improve access to care

- High costs of care mean some individuals with SCD delay or avoid treatment
- The cost of gene therapy will be a barrier to treating eligible patients
  - DMAS intends to participate in the CMS Cell and Gene Therapy Access Model
  - DMAS' actuary has indicated coverage for up to 15 individuals in 2025 to receive gene therapies across several diagnoses

CMS = Centers for Medicare and Medicaid Services, DMAS = Department of Medical Assistance Services

Policy Option 6

The JCHC could introduce a Section 1 bill directing the Department of Medical Assistance Services (DMAS) to include information on the status of the Commonwealth's participation in the Cell and Gene Therapy Access Model in DMAS's annual report on covered medications, services, and treatments for sickle cell disease.

Health plan coverage and utilization management can hinder access

- Nationally and in Virginia, more than half of individuals with SCD are covered through Medicaid or the Children's Health Insurance Program
- Health insurance plans may not provide coverage for all SCD-related needs
- Differing utilization management guidelines across insurers create delays in accessing care

Policy Option 7

The Joint Commission on Health Care could introduce a Section 1 bill directing the DMAS to develop a plan for a comprehensive sickle cell disease program to ensure that provisions governing access to sickle cell disease treatment are consistent across Medicaid managed care organizations.

There may be opportunities to expand Medicaid coverage of SCD

- Existing federal flexibilities offer opportunities to expand coverage and access to services:
  - **Optional SCD benefit** allows states to cover additional SCD services that are not included in the state plan or increase reimbursement rates for SCD services
  - **Medicaid Health Homes for SCD** allow providers to access an enhanced federal match

Policy Option 8

The JCHC could submit a Section 1 bill directing DMAS to determine the feasibility of participating in an optional Medicaid benefit for sickle cell disease or establishing Medicaid Health Homes to coordinate care and provide comprehensive sickle cell treatment services for individuals with sickle cell disease.

Opportunity for public comment

- Submit written public comments by close of business on Friday, December 6th

  Email: jchcpubliccomments@jchc.virginia.gov

  Mail: 411 E. Franklin Street, Suite 505

  Richmond, VA 23219

NOTE: All public comments are subject to FOIA and must be released upon request.

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