The Florida Senate

BILL ANALYSIS AND FISCAL IMPACT STATEMENT

(This document is based on the provisions contained in the legislation as of the latest date listed below.)

Prepared By: The Professional Staff of the Committee on Health Policy

BILL:	CS/SB 1408
INTRODUCER:	Committee on Health Policy and Senator Davis
SUBJECT:	Sickle Cell Program
DATE:	April 5, 2023
REVISED:	

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Stovall	Brown	HP	**Fav/CS**
2.			AHS	
3.			FP	

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/SB 1408 establishes a grant program within the Department of Health (department) for the prevention, care, and treatment of sickle cell disease (SCD) and sickle cell trait or sickle cell trait carriers and for community-based educational programs concerning the prevention, care, and treatment of the disease. The act is named the "Sickle Cell Disease and Sickle Cell Trait Prevention, Care, and Treatment Act."

The department must develop application criteria and standards of eligibility for funds under the grant program. The bill directs that priority for grant awards be given to established SCD and sickle cell trait or sickle cell trait carrier community-based applicants throughout the state. Further priority must be given to ensuring the establishment of SCD and sickle cell trait or sickle cell trait carrier centers in underserved areas with a higher population of SCD and sickle cell trait or sickle cell trait carrier patients.

The department is also tasked with conducting a study to determine the prevalence, impact, and needs of patients diagnosed with SCD or sickle cell trait or sickle cell trait carriers in this state.

The bill is estimated to have a significant negative fiscal impact. See Section V. of this analysis.

The bill provides an effective date of July 1, 2023.

II. Present Situation:

Sickle Cell Disease and Sickle Cell Trait

Sickle cell disease is a group of inherited red blood cell disorders. Red blood cells contain hemoglobin, a protein that carries oxygen. Healthy red blood cells are round, and they move through small blood vessels to carry oxygen to all parts of the body. In someone who has SCD, the hemoglobin is abnormal, which causes the red blood cells to become hard and sticky and look like a C-shaped farm tool called a sickle. The sickle cells die early, which causes a constant shortage of red blood cells. Also, when they travel through small blood vessels, they get stuck and clog the blood flow. This can cause pain and other serious health complications such as infection, acute chest syndrome, and stroke.[1]

The exact number of people living with SCD in the U.S. is unknown. The U.S. Centers for Disease Control and Prevention (CDC) estimates:[2]

- SCD affects approximately 100,000 Americans.
- SCD occurs among about one out of every 365 Black or African-American births.
- SCD occurs among about one out of every 16,300 Hispanic-American births.
- Roughly 7.7 percent of Black or African-American babies are born with sickle cell trait (SCT).

There are several types of SCD. The specific type a person has depends on the genes they inherited from their parents. People with SCD inherit genes that contain instructions, or code, for abnormal hemoglobin. The most common types of SCD include:[3]

- HbSS. People who have this form of SCD inherit two genes, one from each parent, that code for hemoglobin "S." Hemoglobin S is an abnormal form of hemoglobin that causes the red cells to become rigid, and sickle shaped. This is commonly called sickle cell anemia and is usually the most severe form of the disease.
- HbSC. People who have this form of SCD inherit a hemoglobin "S" gene from one parent and a gene for a different type of abnormal hemoglobin called "C" from the other parent. This is usually a milder form of SCD.
- HbS beta thalassemia. People who have this form of SCD inherit a hemoglobin "S" gene from one parent and a gene for beta thalassemia, another type of hemoglobin abnormality, from the other parent. There are two types of beta thalassemia: "zero" (HbS beta^0) and "plus" (HbS beta$^+$). Those with HbS beta^0-thalassemia usually have a severe form of SCD. People with HbS beta$^+$-thalassemia tend to have a milder form of SCD.

There also are a few rare types of SCD, such as HbSD, HbSE, and HbSO. People who have these forms of SCD inherit one hemoglobin "S" gene and one gene that codes for another abnormal type of hemoglobin ("D", "E", or "O"). The severity of these rarer types of SCD varies.

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[1] Centers for Disease Control and Prevention, Sickle Cell Disease available at: https://www.cdc.gov/ncbddd/sicklecell/facts.html#:~:text=In%20someone%20who%20has%20SCD,shortage%20of%20red%20blood%20cells. (last visited March 29, 2023)

[2] Centers for Disease Control and Prevention, Data and Statistics on Sickle Cell Disease, available at: https://www.cdc.gov/ncbddd/sicklecell/data.html (last visited March 29, 2023).

[3] *Id.*

SCD is diagnosed with a simple blood test. In children born in the U.S., it most often is found at birth during routine newborn screening tests at the hospital. In addition, SCD can be diagnosed while the baby is in the womb. Because children with SCD are at an increased risk of infection and other health problems, early diagnosis and treatment are important.

People with SCD may start to have signs of the disease during the first year of life, usually around five months of age. Symptoms and complications of SCD are different for each person and can range from mild to severe.

Management of SCD is focused on preventing and treating pain episodes, anemia, and other complications. Prevention strategies include lifestyle behaviors as well as medical screening and interventions to prevent SCD complications. Lifestyle behaviors might include drinking plenty of water and avoiding getting too hot or cold, high altitudes, or extreme exertion. Vaccines can prevent against harmful infections. Other intervention strategies might include prevention of severe anemia through blood transfusions which has its own set of complications such as iron overload that can cause life-threatening damage to the liver, heart, and other organs.

SCD is a disease that worsens over time. Currently the Food and Drug Administration (FDA) has approved four treatments. However, the only therapy approved by the FDA that may be able to cure SCD is a bone marrow or stem cell transplant, which can be very risky.[4]

Sickle cell trait (SCT) presents itself in people who inherit one sickle cell gene and one normal gene. People with SCT usually do not have any symptoms of SCD, although in rare cases they might experience complications of SCD. A person with SCT can pass the trait on to their children. SCT is diagnosed with a blood test.[5]

Florida's Sickle Cell Program

The Sickle Cell Program is found in s. 381.815, F.S. Under this section, the department is required, to the extent that resources are available, to provide education to Floridians about SCD, work cooperatively with not-for-profit centers to provide community-based education, patient teaching and counseling, and to encourage diagnostic screening,. The department is directed to make grants or enter into contract with not-for-profit centers.

Office of Minority Health and Health Equity

The Office of Minority Health and Health Equity within the department is responsible for developing and promoting the statewide implementation of policies, programs, and practices that increase health equity in this state, including, but not limited to, increased access to, and quality of health care services for, racial and ethnic minority populations. As a part of this responsibility, the department administers the Closing the Gap grant program found in s. 381.7353, F.S. A Closing the Gap grant proposal must address one or more of 12 priority areas. One of those areas is decreasing racial and ethnic disparities in morbidity and mortality rates relating to SCD.

[4] Center for Disease Control and Prevention, https://www.cdc.gov/ncbddd/sicklecell/facts.html (last visited March 29, 2023).
[5] Centers for Disease Control and Prevention, Sickle Cell Trait available at: https://www.cdc.gov/ncbddd/sicklecell/traits.html (last visited March 29, 2023)

Closing the Gap grants are awarded on a match basis with one dollar in local matching funds required for each three dollars in grant payment from the state. Exceptions are based on population in which case in-kind contributions may be used to offset some or all of the required match and grant awards to Front Porch Florida Communities are exempt from providing a match.[6]

The amount of a grant award is based on the merits of the application. Awards are made on an annual basis and may be renewed upon application and approval by the department, subject to the achievement of quality standards, objectives, and outcomes and to the availability of funds. The Closing the Gap grant program is subject to a specific appropriation provided in the General Appropriations Act.[7]

The 2022-2023 General Appropriations Act provided $238,860 to the Sickle Cell Disease Association of Florida, Inc. – Sickle Cell Outreach[8] and $3 million to the Foundation for Sickle Cell Disease Research.[9]

III. Effect of Proposed Changes:

The act is named the "Sickle Cell Disease and Sickle Cell Trait Prevention, Care, and Treatment Act."

The bill amends s. 381.815, F.S., by rewriting subsection (3) of that statute to establish a grant program to be administered by the department for the prevention, care, and treatment of SCD and sickle cell trait or sickle cell trait carriers and for community-based educational programs concerning the disease. All grant funds issued under the bill must be used for these purposes. The educational programs must include an outreach program that provides for the dissemination of information relating to the prevention, care, and treatment of SCD and sickle cell trait or sickle cell trait carriers.

The bill directs the department to develop application criteria and standards of eligibility for groups or organizations. Established SCD and sickle cell trait or sickle cell trait carrier community-based applicants must be given priority. Further priority must be given to ensuring the establishment of SCD and sickle cell trait or sickle cell trait carrier centers in underserved areas with a higher population of SCD and sickle cell trait or sickle cell trait carrier patients.

The department is also tasked under the bill with conducting a study to determine the prevalence, impact and needs of patients diagnosed with SCD or sickle cell trait or sickle cell trait carriers in this state.

The department is directed to adopt rules necessary to implement the bill's provisions.

The bill provides an effective date of July 1, 2023.

[6] *See* s. 381.7356(2), F.S.
[7] *See* s. 381.7356(6) and (7), F.S.
[8] *See* HB 5001 (2022) General Appropriations Act at line 524.
[9] See HB 5001 (2022) General Appropriations Act at line 476.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

D. State Tax or Fee Increases:

None.

E. Other Constitutional Issues:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

None.

C. Government Sector Impact:

The Department of Health reports it will need four full-time equivalent (FTE) positions and $431,944 ($412,588 of which would be recurring) to fund those positions and their corresponding expenses, in order to implement CS/SB 1408. The department also estimates the need for $300,000 to conduct the study, another $300,000 for the outreach campaign, and $2.5 million for the grant program (assuming 10 contracts at $250,000 each) on a recurring basis. Under the department's estimate, the bill has a recurring negative fiscal impact of approximately $3.51 million.[10]

VI. Technical Deficiencies:

The CS removes a provision from the underlying bill that would have directed the department to develop and maintain a voluntary sickle cell disease registry for persons diagnosed with sickle cell disease. However, on lines 23-24, the CS maintains the underlying bill's amendment to the

[10] Email from the Department of Health to the Senate Appropriations Committee on Health and Human Services, April 3, 2023, on file with the Senate Committee on Health Policy.

catchline of s. 381.815, F.S., to indicate the existence of the "voluntary registry." An amendment to the CS should be considered to remove that catchline language from the bill.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill substantially amends section 381.815 of the Florida Statutes.

IX. Additional Information:

A. Committee Substitute – Statement of Substantial Changes:
(Summarizing differences between the Committee Substitute and the prior version of the bill.)

CS by Health Policy on April 4, 2023:
The CS expands the scope of the bill to include sickle cell trait and sickle cell trait carriers. The CS also removes from the underlying bill a duty for the department to develop and maintain a voluntary sickle cell disease registry for persons diagnosed with sickle cell disease.

B. Amendments:

None.