HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: CS/HB 247 Sickle Cell Program
SPONSOR(S): Healthcare Regulation Subcommittee, Campbell
TIED BILLS: **IDEN./SIM. BILLS:**

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Healthcare Regulation Subcommittee	15 Y, 0 N, As CS	Osborne	McElroy
2) Health Care Appropriations Subcommittee		Aderibigbe	Clark
3) Health & Human Services Committee			

SUMMARY ANALYSIS

Sickle cell disease (SCD) is an inherited disease caused by abnormal hemoglobin in red blood cells, which causes the red blood cells to become hard and sticky. The abnormal red blood cells cause blockages in blood vessels that over time cause severe damage to vital organs and tissue. This can lead to episodes of pain or other health problems such as strokes, organ failure, eye problems, and infections. It affects approximately 100,000 people nationwide, 90 percent of which are people of African descent.

Children with SCD are at an increased risk of infection and other health problems which makes early diagnosis and treatment important. Management of SCD is focused on preventing and treating pain episodes and other complications, the severity of which differ for each person. The complications associated with SCD worsen as people age, but treatments and prevention strategies can mitigate complications and lengthen the lives of people with SCD.

Closing the Gap (CTG), a program under the Department of Health (DOH) awarded three grants for projects relating to sickle cell disease in Fiscal Year 2020-2021. The CTG is intended to improve health outcomes and eliminate racial and ethnic health disparities in Florida by providing grants to increase community-based health and disease prevention activities.

CS/HB 247 establishes a grant program under DOH for the prevention, care, and treatment of sickle cell disease and sickle cell trait and for community-based educational programs concerning the disease. The bill establishes requirements for the community-based outreach program and requires all program grant funds to be used for the prevention, care, and treatment of SCD and sickle cell trait or for educational programs concerning SCD.

The bill requires DOH to develop application criteria and standards of eligibility for applicants. DOH is required to prioritize established, community-based applicants and projects establishing sickle cell disease centers in underserved areas with a higher population of SCD and sickle cell trait patients.

The bill also requires DOH to conduct a study to determine the prevalence, impact, and needs of patients diagnosed with SCD and sickle cell trait in Florida.

The bill has a significant, indeterminant, negative fiscal impact on DOH.

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

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Background

Sickle Cell Disease

Sickle cell disease (SCD) is the most common inherited blood disorder in the United States—approximately 100,000 Americans have SCD.[1] It is caused by a specific variation of the hemoglobin genes responsible for instructing the body on how to build the hemoglobin proteins that carry oxygen in our blood. The variation that causes SCD is a mutation to the beta-globin gene known as HbS.

Hemoglobin carries oxygen inside red blood cells from the lungs to other parts of the body. Red blood cells with normal hemoglobin are smooth, round, and glide easily through blood vessels.[2] In people with SCD, abnormal hemoglobin forms long fibers that cause red blood cells to buckle into a sickle-shape. These sickle-shaped red blood cells are sticky and unstable; they lead to a constant shortage of red blood cells in the body and pile up to create blockages in blood vessels that over time cause severe damage vital organs and tissue.[3]

A person must inherit the HbS gene from both parents to inherit symptomatic SCD. If a person inherits the HbS gene from only one parent, then the person has sickle cell trait. People with sickle cell trait do not have SCD and have the same life expectancy as the general population; however, they are a carrier of SCD, thus increasing the likelihood of having a child with SCD if they have a child with another person with sickle cell trait.[4] When both parents have sickle cell trait, there is a 25 percent chance their child will inherent the HbS gene from both parents and have SCD. A child of those same parents would have a 50 percent chance of inheriting sickle cell trait, and a 25 percent chance of no sickle cell inheritance.[5]

SCD occurs most often among people with ancestry that can be traced to parts of the world where malaria is or was common.[6] Individuals who carry the sickle cell trait have been shown to have some protective advantage against malaria; as a result, the frequency of sickle cell carriers is high in malaria-endemic areas and among those whose lineage can be traced to those regions. [7]

In the US, SCD occurs in about one out of every 365 African American births, and one out of every 16,300 Hispanic-American births.[8] Approximately 1 in 13 African Americans carry the sickle cell trait.[9]

Diagnosis and Treatment of SCD

[1] National Heart, Lung, and Blood Institute, *What is Sickle Cell Disease?*, available at https://www.nhlbi.nih.gov/health/sickle-cell-disease (last visited March 20, 2023).

[2] Centers for Disease Control and Prevention, *What is Sickle Cell Disease?,* available at https://www.cdc.gov/ncbddd/sicklecell/facts.html (last visited March 24, 2023).

[3] AHCA, *Florida Medicaid Study of Enrollees with Sickle Cell Disease*, February 1, 2023, available at https://ahca.myflorida.com/content/download/20771/file/Florida_Medicaid_Study_of_Enrollees_with_Sickle_Cell_Disease.pdf (last viewed March 24, 2023).

[4] *Id*.

[5] *Id.*

[6] Centers for Disease Control and Prevention, *Data & Statistics on Sickle Cell Disease,* available at https://www.cdc.gov/ncbddd/sicklecell/data.html (last visited March 24, 2023).

[7] Centers for Disease Control and Prevention, *About Malaria – Biology,* available at https://www.cdc.gov/malaria/about/biology/index.html#tabs-1-4 (last visited March 24, 2023).

[8] *Id.*

[9] *Id*.

Children with SCD are at an increased risk of infection and other health problems which makes early diagnosis and treatment important.[10] In Florida, newborns are required to be screened for SCD within 1 week after birth.[11] SCD can also be diagnosed prenatally through diagnostic tests that identify chromosomal or genetic abnormalities.[12]

People with SCD start to show signs of disease in the first year of life. Management of SCD is focused on preventing and treating pain episodes and other complications, the severity of which differ for each person.[13] The complications associated with SCD worsen as people age, but treatments and prevention strategies can mitigate complications and lengthen the lives of people with SCD.[14]

People with SCD are advised to adjust lifestyle behaviors in order to mitigate complications, for example avoiding situations with exposure to low oxygen levels such high altitudes and intense exercise.[15] Other prevention strategies focus on preventing specific complications of SCD, such as infection, vision loss, stroke, and severe anemia.[16] Daily oral penicillin is the standard of care for children with SCD because chronic damage to the spleen increases the risk of life-threatening pneumococcal bacterial infection.[17] Routine screening with a specialized ultrasound device is used to monitor for stroke risk, and blood transfusions may be used to help prevent a stroke or alleviate severe anemia.[18]

The only U.S. Food and Drug Administration-approved therapy that may be able to cure SCD is a bone marrow or stem cell transplant.[19] These treatments are estimated to cost $1 million to $2 million per person and are only available at a limited number of transplant centers.[20]

Closing the Gap Grants for Sickle Cell

The Department of Health Office of Minority Health and Health Equity (office) is the coordinating office for consultative services in the areas of cultural and linguistic competency, partnership building, and program development and implementation to address the health needs of Florida's minority and underrepresented populations statewide. The office administers multiple health promotion programs including the "Closing the Gap" (CTG) grant program.[21] In 2000, the Legislature created the CTG grant program to improve health outcomes and eliminate racial and ethnic health disparities in Florida by providing grants to increase community-based health and disease prevention activities.[22] In order to qualify for CTG funding, a grant proposal must address a priority area listed in statute.[23]

In 2015, the Legislature added decreasing racial and ethnic disparities in morbidity and mortality rates relating to sickle cell disease to the list of priority areas that could receive funding from the CTG program.[24]

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[10] *Supra*, note 2.
[11] S. 383.14(2), F.S., and rule 64C-7.002, F.A.C.
[12] Centers for Disease Control and Prevention, National Center on Birth Defects and Developmental Disorders, *What You Should Know About Sickle Cell Disease and Pregnancy*, available at https://www.cdc.gov/ncbddd/sicklecell/documents/scd-factsheet_scd--pregnancy.pdf (last viewed March 24, 2023).
[13] *Supra*, note 2.
[14] Centers for Disease Control and Prevention, *Complications of Sickle Cell Disease,* available at https://www.cdc.gov/ncbddd/sicklecell/complications.html (last visited March 24, 2023).
[15] *Supra*, note 2.
[16] *Id.*
[17] *Supra,* note 2, at 10-12. Hydroxyurea is the standard of care for people as young as 9 months old; L-Glutamine is recommended for adults and children age 5 and older; Voxelotor is recommended for adults and children age 4 and older; Crizanlizumab is recommended for people age 16 and older; and opioids and iron chelating agents are also often used.
[18] *Supra*, note 2.
[19] *Supra* note 3.
[20] *Supra* note 2.
[21] Florida Department of Health, *Minority Health,* available at http://www.floridahealth.gov/%5C/programs-and-services/minority-health/index.html (last visited March 24, 2023).
[22] Ss. 381.7353–381.7356, F.S.
[23] *See* s. 381.7355, F.S., for the complete list of qualifying priority areas.
[24] Ch. 2015-10, L.O.F.

The amount of award per applicant may vary, as awards are based on the merit of the grant application and there are no minimum or maximum amounts for grant awards.[25] Projects receiving grants are required to provide local matching funds of one dollar for every three dollars awarded.[26] In counties with populations greater than 50,000, up to 50 percent of the local matching funds may be in-kind in the form of free services or human resources.[27] In counties with populations of 50,000 or less, local matching funds may be provided entirely through in-kind contributions.[28]

Since 2020, three CTG grants have been awarded to sickle cell related projects.

CTG Sickle Cell Grants FY 2020-2021[29]		
Organization	Project Scope	Award
Foundation for Sickle Cell Research (FSCDR)	The provider will recruit a Telehealth Provider and enroll Eligible Patients in Provider's Program.	$200,000.00
Sickle Cell Disease Foundation	The provider will coordinate education, screening, and awareness activities for eligible minorities in Leon, Gadsden, Madison, and Jefferson counties to increase knowledge and understanding of Sickle Cell Disease.	$116,374.00
Foundation for Sickle Cell Research (FSCDR)	The Provider will implement a sickle cell community-integrated health network in ten counties that utilizes a centralized, coordinated model for service provision.	$3,000,000.00

Effect of the Bill

CS/HB 247 establishes a grant program at the DOH for the purpose of prevention, care, and treatment of sickle cell disease (SCD) and sickle cell trait, and for community-based educational programs concerning the disease. The bill establishes requirements for the community-based outreach program and requires all program grant funds to be used for the prevention, care, and treatment of SCD and sickle cell trait, or for educational programs concerning SCD.

The bill instructs DOH to develop application criteria and standards of eligibility for applicants. DOH is required to prioritize established, community-based applicants and projects establishing sickle cell disease centers in underserved areas with a higher population of SCD or sickle cell trait patients.

B. SECTION DIRECTORY:

Section 1: Provides a name for the act: "Sickle Cell Prevention, Care, and Treatment Act."
Section 2: Amends s. 381.815, F.S., relating to sickle-cell programs.
Section 3: Provides an effective date of July 1, 2023.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

[25] S. 381.7356(4), F.S. *See also,* Florida Department of Health, *Application Guidelines FY 2021-2023*, available at http://www.floridahealth.gov/about/administrative-functions/purchasing/grant-funding-opportunities/RFA20-005.pdf (last viewed Mar. 15, 2021).
[26] S. 381.7356(2), F.S.
[27] S. 381.7356(2)(a), F.S.
[28] S. 381.7356(2)(b), F.S.
[29] Email from Gangul Gabadage, Deputy Legislative Director, Department of Health, *HB 247 Agency Analysis & Info Request*, March 15, 2023, on file with the Healthcare Regulation Subcommittee.

1. Revenues:

   None.

2. Expenditures:

   The bill provides, to the extent that resources are available, that DOH establish the grant program. The bill has a significant, indeterminant, negative fiscal impact on DOH related to the funding of the proposed grant program. DOH may request resources through the Legislative Budget Request process.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

   None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

None.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

   The bill does not appear to affect county or municipal governments.

2. Other:

   None.

B. RULE-MAKING AUTHORITY:

The bill provides sufficient rule-making authority to DOH to implement the provisions of the bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/COMMITTEE SUBSTITUTE CHANGES

On March 28, 2023, the Healthcare Regulation Subcommittee adopted an amendment and reported the bill favorably as a committee substitute. The amendment expanded the applicability of programs established in the bill to include individuals with sickle cell trait. The amendment also removed the provisions related to the creation of a voluntary registry for individuals with sickle cell disease from the bill.

The analysis is drafted to the committee substitute as passed by the Healthcare Regulation Subcommittee.