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 Fiscal Policy

BILL:	CS/SB 1352
INTRODUCER:	Appropriations Committee on Health and Human Services; Senators Rouson and Davis
SUBJECT:	Sickle Cell Disease Medications, Treatment, and Screening
DATE:	April 19, 2023
REVISED:	

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Stovall	Brown	HP	**Favorable**
2.	McKnight	Money	AHS	**Fav/CS**
3.	Stovall	Yeatman	FP	**Pre-meeting**

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/SB 1352 requires the Agency for Health Care Administration (AHCA) to conduct a biennial review of Medicaid enrollees with sickle cell disease (SCD) and report the findings and recommendations from the preceding two year period. The first report is due November 1, 2024, and by November 1 of every other year thereafter, and reports are to be submitted to the Governor, President of the Senate, Speaker of the House of Representatives, the Office of Minority Health and Health Equity, and the Rare Disease Advisory Council, and published by the AHCA on a publicly accessible website.

The objective of the review is to determine whether available covered medications, treatment, and services are adequate to meet the needs of Medicaid enrollees diagnosed with SCD and whether the AHCA should seek coverage of additional medications, treatment, or services.

The AHCA is also required to assess existing payment methodologies for approved SCD treatments and medications in the inpatient setting and whether they result in barriers to access. If barriers to access are identified, the AHCA must assess whether the payment methodologies may be modified or improved.

In addition, the bill:

- Requires the Department of Health (DOH) to contract with a community-based sickle cell disease medical treatment and research center to establish and maintain a registry to track

outcome measures of newborns who are identified as carrying a sickle cell hemoglobin variant.
- Requires a screening provider to notify the primary care physician of an infant who tests positive for sickle cell hemoglobin variant and to submit the results of the screening to the DOH for inclusion in the sickle cell registry.
- Requires the primary care physician to provide the information on the availability and benefits of genetic counseling to the parent or guardian of the newborn.

The bill authorizes $250,000 in nonrecurring funds from the General Revenue Fund to the DOH to contract with a community-based SCD medical treatment and research center to establish and maintain the sickle cell registry.

The bill will have an indeterminate, significant negative fiscal impact to the AHCA and the DOH. *See* Section V of this analysis.

The bill takes effect on July 1, 2023.

II. Present Situation:

Sickle Cell Disease and Sickle Cell Trait

Sickle cell disease (SCD) 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]

[1] U.S. 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 Mar. 29, 2023)
[2] U.S. 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 Mar. 29, 2023).
[3] *Id.*

- 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.

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 U.S. 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]

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]

[4] U.S. Centers for Disease Control and Prevention, *What is Sickle Cell Disease?, available at* https://www.cdc.gov/ncbddd/sicklecell/facts.html (last visited Mar. 29, 2023).
[5] U.S. Centers for Disease Control and Prevention, *Sickle Cell Trait, available at* https://www.cdc.gov/ncbddd/sicklecell/traits.html (last visited Mar. 29, 2023)

Florida Medicaid Study of Enrollees with Sickle Cell Disease

In the Fiscal Year 2022-2023 General Appropriations Act,[6] the AHCA was directed to conduct a review and provide a written report concerning the impact of SCD in the Florida Medicaid program. As directed, the AHCA contracted with the Florida Medical School Quality Network, including key personnel of the Foundation for Sickle Cell Disease Research and the Sickle Care and Research Network, which is a dedicated SCD medical treatment and research center headquartered in Hollywood, Florida, and maintains a sickle cell patient database and tracks SCD outcome measures. The report was submitted on February 1, 2023.[7]

Findings in this report indicate the number of people with SCD in the Florida Medicaid program (program) averages 7,328 people per year. The prevalence rate of SCD in the program is twice as high as the national average for Medicaid and the program has one of the highest numbers of SCD patients in the U.S., indicating a disproportionate impact from a national perspective. The program's SCD population was predominately female (58 percent), young (median age 18 years), and Black (63 percent). Geographically, the highest number of Medicaid SCD patients live in Central and South Florida.

Further, the report states that over the last four years, nearly all Medicaid SCD patients were evaluated at least once by a physician, 85 percent were evaluated and treated in an outpatient clinic, 61 percent were treated in the ER, and 52 percent were hospitalized. Stroke screening with transcranial doppler ultrasound in Medicaid children and adolescents with SCD was very low. SCD-relevant medications were prescribed and filled in 77 percent of Medicaid SCD patients. Guideline-recommend treatments with penicillin or hydroxyurea were observed in 58 percent or 22 percent, respectively, of program SCD patients, indicating a gap between use and evidence-based treatments. Newer therapies with L-glutamine, voxelotor, or crizanlizumab have been used in the program's SCD population, albeit at low utilization. Supportive care with iron chelating agents or opioids have also been used in the program's SCD population, at low utilization.

Among medical services in the program, the highest expenditure was inpatient hospitalization, although this amount has decreased each year for the past four years. The total expenditures for program recipients with SCD in calendar year 2021 was over $91 million, which averaged approximately $4,500 per person with SCD. In comparison, this per capita Medicaid SCD spending was below the amount spent on Medicaid recipients with diabetes in State Fiscal Year 2020-2021, despite SCD having higher morbidity and mortality. Within the Medicaid SCD population, 54 percent were determined high-utilizers of acute care facilities. Their expenditures made up 70 percent of the total cost of care for the SCD population. There was slightly higher prevalence of high-utilizers in West Florida compared to other regions. Clinical treatment centers specializing in SCD were identified in Florida and found predominantly in Central and South Florida.

[6] *See* Chapter 2022-156, Laws of Fla., Specific Appropriation 189.
[7] *See* Agency for Health Care Administration, *Florida Medicaid Study of Enrollees with Sickle Cell Disease, available at* Florida_Medicaid_Study_of_Enrollees_with_Sickle_Cell_Disease.pdf (myflorida.com) (last visited Mar. 29, 2023).

Office of Minority Health and Equity

The Office of Minority Health and Health Equity is established in the Department of Health (DOH).[8] It 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.

Rare Disease Advisory Council

Florida's Rare Disease Advisory Council (RDAC) was established in 2021, in s. 381.99, F.S., to assist the DOH in providing recommendations to improve health outcomes for individuals residing in this state who have a rare disease.[9] Rare diseases include genetic disorders, infectious diseases, cancers, and other various pediatric and adult conditions. SCD is classified as a genetic and rare disease.[10]

The RDAC is composed of representatives from state agencies, health care providers, researchers, advocacy groups, insurance and pharmaceutical industries, as well as individuals with rare diseases and caregivers of individuals with rare diseases.[11] Council members hold a shared vision: to improve health outcomes for individuals residing in Florida who have rare diseases.[12]

III. Effect of Proposed Changes:

Section 1 creates s. 383.147, F.S., to require the Department of Health (DOH) to contract with a community-based sickle cell disease (SCD) medical treatment and research center to establish and maintain a registry to track outcome measures of newborns who are identified as carrying a sickle cell hemoglobin variant. The bill requires a screening provider to notify the primary care physician of an infant who tests positive for sickle cell hemoglobin variant and to submit the results of the screening to the DOH for inclusion in the sickle cell registry. The primary care physician must provide information on the availability and benefits of genetic counseling to the parent or guardian of the newborn.

The bill requires the DOH to establish a system to ensure that the sickle cell research center notifies the parent or guardian of a child included in the registry that a follow-up consultation with a physician is recommended, at least once during early adolescence and once during late adolescence. The bill also requires the DOH to provide individuals who are 18 years of age and that are included in the registry with information regarding available educational services, genetic counseling, and other beneficial resources.

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[8] Section 20.43(9), F.S.
[9] *See* Department of Health, *Rare Disease Advisory Council*, *available at* https://www.floridahealth.gov/provider-and-partner-resources/rdac/index.html (last visited Mar. 31, 2023).
[10] *See* NIH National Center for Advancing Translational Sciences, *Genetic and Rare Diseases Information Center*, *available at* https://rarediseases.info.nih.gov/diseases?category=&page=1&letter=&search=sickle%20cell (last visited Mar. 31, 2023).
[11] A list of the council members as of July 1, 2022, is available in the Rare Disease Advisory Council Annual Report dated July 1, 2022, *available at* https://www.floridahealth.gov/provider-and-partner-resources/rdac/_documents/Rare-Disease-Advisory-Council-Legislative-Report_2022.pdf (last visited Mar. 31, 2023).
[12] *Id.* Executive Summary.

The bill provides rulemaking authority to the DOH to create the registry and requires the DOH to adopt rules to establish a process for removing individuals from the registry.

Section 2 creates s. 409.91235, F.S., to require the Agency for Health Care Administration (AHCA), in consultation with the Florida Medical Schools Quality Network and a dedicated SCD medical treatment and research center that maintains a sickle cell patient database and tracks SCD outcome measures, to biannually conduct a review and develop a written report that details the review findings.

The objective of the review is to determine whether available covered medications, treatment, and services are adequate to meet the needs of Medicaid enrollees diagnosed with SCD and whether the AHCA should seek coverage of additional medications, treatment, or services.

The first report is due November 1, 2024, and by November 1 of every other year thereafter, and reports are to be submitted to the Governor, President of the Senate, Speaker of the House of Representatives, the Office of Minority Health and Health Equity, and the Rare Disease Advisory Council, and published by the AHCA on a publicly accessible website.

The bill also requires the AHCA to assess their existing Medicaid payment methodologies for approved SCD treatments and medications in the inpatient setting and whether such payment methodologies result in barriers to access. If barriers to access are identified, the AHCA must assess whether the payment methodologies may be modified or improved.

Section 3 authorizes $250,000 in nonrecurring funds from the General Revenue Fund to the DOH to contract with a community-based SCD medical treatment and research center to establish and maintain the sickle cell registry.

Section 4 provides an effective date of July 1, 2023.

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 (DOH) indicates it will need $3,096,181 in recurring general revenue funds to meet the requirements of the bill, including but not limited to:

- One (1) full-time equivalent (FTE) position with associated salary rate of 59,776, and $85,152 in salary and benefits.
- $2,750,000 to contract with a vendor for the sickle cell registry.
- $250,000 to contract with a vendor for a sickle cell campaign.[13]

For Fiscal Year 2023-2024, the bill authorizes $250,000 in nonrecurring funds from the General Revenue Fund to the DOH to contract with a community-based sickle cell disease medical treatment and research center to establish and maintain the sickle cell registry.

The Agency for Health Care Administration (AHCA) may incur costs to conduct the review and develop the report every two years. The AHCA has not provided an estimate of CS/SB 1352's fiscal impact, but was appropriated $250,000 in nonrecurring general revenue funds in Fiscal Year 2022-2023 for a comparable review and report.[14]

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill creates the following sections of the Florida Statutes: 383.147 and 409.91235.

[13] Email from the Department of Health to Senate Appropriations Committee on Health and Human Services (Apr. 10, 2023) (on file with the Senate Appropriations Committee on Health and Human Services).
[14] Chapter 2022-156, Specific Appropriation 189.

IX. Additional Information:

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

CS by Appropriations Committee on Health and Human Services on April 12, 2023:
The committee substitute:

- Requires the Department of Health (DOH) to contract with a community-based sickle cell disease (SCD) medical treatment and research center to establish and maintain a registry, which tracks SCD outcome measures, for newborns who are identified as carrying a sickle cell hemoglobin variant.
- Requires a screening provider to notify the primary care physician of an infant who tests positive for sickle cell hemoglobin variant and to submit the results of the screening to the DOH for inclusion in the sickle cell registry.
- Requires the primary care physician to provide the parent or guardian of the newborn or infant information regarding the availability and benefits of genetic counseling.
- Requires the DOH to:
  - Adopt a rule to create a process for a parent or guardian of a newborn to request to have their child removed from the registry.
  - Establish a system to ensure that the sickle cell research center notifies the parent or guardian of a child included in the registry that a follow-up consultation with a physician is recommended, at least once during early adolescence and once during late adolescence.
  - Make every reasonable effort to notify individuals who are 18 years of age that they may be removed from the registry, and requires the DOH to adopt a rule to create a process for such notification.
  - Provide individuals who are 18 years of age and that are included in the registry with information regarding available educational services, genetic counseling, and other beneficial resources.
- Provides rulemaking authority to the DOH.
- Requires the Agency for Health Care Administration (AHCA) to consult with the Florida Medical Schools Quality Network and a dedicated SCD medical treatment and research center that maintains a sickle cell database and tracks SCD outcomes for the bill's underlying biannual review and written report.
- Authorizes $250,000 in nonrecurring funds from the General Revenue Fund to the DOH to contract with a community-based SCD medical treatment and research center to establish and maintain the sickle cell registry.

B. Amendments:

None.