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:	SB 1352
INTRODUCER:	Senators Rouson and Davis
SUBJECT:	Medicaid Enrollees with Sickle Cell Disease
DATE:	April 2, 2023
REVISED:	

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Stovall	Brown	HP	**Favorable**
2.			AHS	
3.			FP	

I. Summary:

SB 1352 requires the Agency for Health Care Administration (agency) 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 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 agency should seek coverage of additional medications, treatment, or services.

Under this bill, the first report is due November 1, 2024, 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 agency on a publicly accessible website.

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.

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.

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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.*

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]

Medicaid / SCD Review

In the 2022-2023 General Appropriations Act,[6] the agency was directed to conduct a review and provide a written report concerning the impact of SCD in the Florida Medicaid program. As directed, the agency 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 sickle cell disease (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 Florida Medicaid averages 7,328 people per year. The prevalence rate of SCD in Florida Medicaid is twice as high as the national average for Medicaid and Florida Medicaid has one of the highest numbers of SCD patients in the U.S., indicating a disproportionate impact from a national perspective. The Florida Medicaid SCD population was predominately female (58%), young (median age 18 years), and Black (63%). 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% were evaluated and treated in an outpatient clinic, 61% were in an ER, and 52% 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% of Medicaid SCD patients. Guideline-recommend treatments with penicillin or hydroxyurea were observed in 58% or 22%, respectively, of Florida Medicaid SCD patients, indicating a gap between use and evidence-based treatments. Newer therapies with L-

[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)
[6] *See* 2022-156, Laws of Fla., line item 189.
[7] *See* Florida Medicaid Study of Enrollees with Sickle Cell Disease.pdf (myflorida.com) (last visited March 29, 2023).

glutamine, voxelotor, or crizanlizumab have been used in the Florida Medicaid SCD population, albeit at low utilization. Supportive care with iron chelating agents or opioids have also been used in the Florida Medicaid SCD population, at low utilization.

Among medical services in Florida Medicaid, the highest expenditure was inpatient hospitalization, although this amount has decreased each year for the past four years. The total expenditures for Florida Medicaid 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% were determined high-utilizers of acute care facilities. Their expenditures made up 70% 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.

Office of Minority Health and Equity

The Office of Minority Health and Health Equity is established in the Department of Health.[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 Department of Health 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. Sickle cell disease 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]

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[8] Section 20.43(9), F.S.
[9] *See* Department of Health, Rare Disease Advisory Council at: https://www.floridahealth.gov/provider-and-partner-resources/rdac/index.html (last visited March 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 March 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 March 31, 2023).
[12] *Id.* Executive Summary.

III. Effect of Proposed Changes:

SB 1352 creates s. 409.9129, F.S., establishing a biennial review and reporting responsibility for the agency of Medicaid enrollees with sickle cell disease. 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 agency should seek coverage of additional medications, treatment, or services.

The analysis will be based on data collected under the Medicaid program of enrollees diagnosed with SCD, focusing on:

- The number and demographic characteristics of enrollees with SCD;
- Pharmaceutical and medical utilization patterns and costs of these enrollees;
- The number of these enrollees with two or more emergency room visits or hospital inpatient admissions in a 12-month period, the length of stay, and total related expenditures, both medical and pharmaceuticals;
- The number and availability of clinical treatment programs designed or certified to provide health care coordination and access for persons with SCD and the number of those programs contracted with managed care plans per region; and
- An assessment of the agency's payment methodologies for treatment and drug products in the inpatient setting and determining, if these methodologies result in barriers to access, whether the methodologies may be improved with modified or new policies.

The first report is due by November 1, 2024, and every two years thereafter. The report must be submitted to the Governor, President of the Senate, and Speaker of the House of Representatives, the Office of Minority Health and Health Equity, and the Rare Disease Advisory Council. The agency must also publish the report on its website in a manner that is easily accessible by the public.

The agency is required to develop its review and report in consultation with a dedicated sickle cell disease medical treatment and research center that maintains a sickle cell patient database and tracks sickle cell disease outcome measures.

The bill 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 agency may incur costs to gather the information and report every two years. The agency has not provided an estimate of SB 1352's fiscal impact, but the amount appropriated in 2022 for a comparable review and report was $250,000.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill creates section 409.9129 of the Florida Statutes.

IX. Additional Information:

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

None.

B. Amendments:

None.