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 Appropriations Committee on Health and Human Services

BILL:	SB 1352
INTRODUCER:	Senators Rouson and Davis
SUBJECT:	Medicaid Enrollees with Sickle Cell Disease
DATE:	April 11, 2023
REVISED:	

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

I. Summary:

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 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.

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 AHCA on a publicly accessible website.

The bill may pose an indeterminate, significant negative fiscal impact to the AHCA. *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]

- 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] 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.*

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]

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.

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[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)
[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).

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.

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]

[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.

III. Effect of Proposed Changes:

The bill creates s. 409.9129, F.S., establishing a biennial review and reporting responsibility for the Agency for Health Care Administration (AHCA) of Medicaid enrollees with sickle cell disease (SCD). 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 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 AHCA'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 AHCA must also publish the report on its website in a manner that is easily accessible by the public.

The AHCA is required to develop its review and report in consultation with a dedicated SCD medical treatment and research center that maintains a sickle cell patient database and tracks SCD 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 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 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.[13]

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.

[13]Chapter 2022-156, Specific Appropriation 189.