HOUSE OF REPRESENTATIVES STAFF FINAL BILL ANALYSIS

BILL #: CS/CS/CS/HB 1481 Sickle Cell Disease Medications, Treatment, and Screening
SPONSOR(S): Health & Human Services Committee and Health Care Appropriations Subcommittee and Healthcare Regulation Subcommittee, Driskell and others
TIED BILLS: **IDEN./SIM. BILLS:** CS/CS/SB 1352

FINAL HOUSE FLOOR ACTION: 116 **Y's** 0 **N's** **GOVERNOR'S ACTION:** N/A

SUMMARY ANALYSIS

CS/CS/CS/HB 1481 passed the House on May 3, 2023, as CS/CS/SB 1352.

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 making them prone to clogging the flow of blood. This can lead to episodes of pain or other health problems such as strokes, organ failure, eye problems, and infections. It affects 100,000 people nationwide, 90 percent of which are people of African descent.

In 2022, the General Appropriations Act (GAA) included nonrecurring funds for the Agency for Health Care Administration (AHCA) to conduct a review and publish a report of its findings on the availability and utilization of specific services for Medicaid enrollees diagnosed with SCD.

The report, which was published on February 1, 2023, used information from 2018 through 2021 on Medicaid enrollees with SCD to produce the following results:

- On average, 7,328 Medicaid enrollees have SCD, which is twice as high as the national average;
- Enrollees are predominantly female (58%), young (median age 18), and black (63%);
- 85 percent were evaluated or treated in an outpatient clinic setting; 61 percent were evaluated in an emergency room; and 52 percent were admitted for inpatient care in a hospital;
- Stroke screening for children with transcranial doppler ultrasound was only performed at half the rate recommended by national guidelines; and
- 72 clinical treatment programs contract with managed care plans to provide care for individuals with SCD.

The bill codifies the GAA report obligation, requiring AHCA to biannually review and report the same information. Additionally, it requires AHCA to assess 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 AHCA identifies barriers to access, AHCA must assess whether the payment methodologies may be modified or improved.

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. 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 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 appropriates $1,060,804 in recurring funds, $21,355 in nonrecurring funds, and five full time employee positions to DOH, and $250,000 in nonrecurring funds to AHCA, to implement the bill. The bill has no fiscal impact on local government.

Subject to the Governor's veto powers, the effective date of this bill is July 1, 2023.

I. SUBSTANTIVE INFORMATION

A. EFFECT OF 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 mutation in the hemoglobin-Beta gene called HbS. When a child inherits HbS from only one parent, the person may have sickle cell trait, which means they are a carrier of SCD, thus increasing the chance of having a child with SCD if they have a child with another carrier.[2] When both parents have SCD, there is a 25 percent chance their child will have SCD. A child from those same parents also has a 50 percent chance of inheriting sickle cell trait and a 25 percent chance of no sickle cell inheritance.[3]

Hemoglobin transports oxygen from the lungs to other parts of the body. Red blood cells with normal hemoglobin are smooth and round and glide through blood vessels. In people with SCD, abnormal hemoglobin molecules stick to one another and form long, rod-like structures. These structures cause red blood cells to become stiff, assuming a sickle shape, which causes them to pile up and create blockages that can damage vital organs and tissue.[4] SCD can also cause fatigue, which is why it is sometimes called sickle cell anemia.[5]

Diagnosis and Treatment

All newborns in Florida are screened within 1 week after birth for SCD.[6] It can also be diagnosed prenatally by using diagnostic tests that identify chromosomal or genetic abnormalities.[7]

SCD gets worse over time, but treatments exist that can prevent complications and lengthen the lives of people with SCD. 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.[8] The only therapy approved by the FDA that may be able to cure SCD is a bone marrow or stem cell transplant.[9] These treatments are estimated to cost $1 million to $2 million per person and are only available at a limited number of transplant centers.[10]

Florida Medicaid Report on Sickle Cell Disease

In 2022, the Legislature appropriated $250,000 in nonrecurring funds from the General Revenue Fund to the Agency for Health Care Administration (AHCA), in consultation with the Florida Medical Schools Quality Network[11] and a dedicated SCD medical treatment and research center that maintains a sickle

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[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 May 11, 2023).
[2] 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 visited May 11, 2023).
[3] *Id*.
[4] CDC, *What is Sickle Cell Disease?*, available at https://www.cdc.gov/ncbddd/sicklecell/facts.html (last visited May 11, 2023).
[5] Id.
[6] S. 383.14(2), F.S., and rule 64C-7.002, F.A.C.
[7] *Supra* note 4.
[8] *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.
[9] *Supra* note 4.
[10] *Supra* note 2.
[11] The Florida Medical Schools Quality Network is an organization of nine participating medical schools contracted by AHCA to to improve clinical outcomes in managed care plans. Contracted activities must support greater clinical integration for Medicaid enrollees

cell patient database and tracks SCD outcome measures,[12] to conduct a review and publish a report of its findings on the availability and utilization of specific services for Medicaid enrollees diagnosed with SCD.[13] Specifically, the report was required to include detailed information on:

- Age and population demographics;
- Utilization patterns and expenditures for all medical and pharmaceutical services provided; and
- The number of clinical treatment programs who contract with managed care plans and are specifically designed or certified to provide care to individuals with SCD.

The report was published on February 1, 2023, and the results were based on data gathered between 2018 through 2021 on Medicaid enrollees with SCD.[14]

Population Demographics

The average number of Medicaid enrollees with SCD is 7,328, which is twice as high as the national average. Florida and New York have the highest number of Medicaid recipients with SCD. According to the report, the SCD population is predominantly female (58%), young (median age 18), and black (63%). Geographically, the highest number of Florida Medicaid enrollees with SCD live in central and south Florida.

Utilization of Medical and Pharmaceutical Services

Nearly all enrollees with SCD were evaluated by a physician at least once and approximately 85 percent were evaluated or treated in an outpatient clinic setting at least once. Sixty-one percent were evaluated and treated in an emergency room at least once, and those with an emergency room visit had an average of 4.5 visits from 2018 to 2021. Fifty-two percent of enrollees with SCD were admitted for inpatient care in a hospital, with an average of 2.9 inpatient admissions from 2018 to 2021.

National guidelines recommend that children with SCD aged 2-16 should have an annual transcranial doppler ultrasound (TCD) to screen for stroke risk.[15] Florida Medicaid child enrollees had an average of two TCDs over the four-year reporting period, which was below the recommended four TCDs for that period.

Data on medication utilization indicated that 77 percent of Medicaid enrollees with SCD had a pharmacy expenditure for a sickle cell disease-relevant medication, including disease-modifying treatments, prophylactic antibiotics, opioids, or iron chelating agents.

through interdependent and cooperative efforts of all providers. *See* s. 409.975(2), F.S., *see also* Florida Medical Schools Quality Network, available at https://www.fmsqn.org/ (last visited May 11, 2023).

[12] AHCA contracted with the Sickle Care and Research Network, which is a dedicated SCD medical treatment and research center in Hollywood, Florida that maintains a sickle cell patient database and tracks SCD outcome measures.

[13] Ch. 2022-156, Laws of Fla.

[14] *Supra* note 2.

[15] National Heart, Lung, and Blood Institute, Evidence-Based Management of Sickle Cell Disease: Expert Panel Report, 2014, available at https://www.nhlbi.nih.gov/health-topics/evidence-based-management-sickle-cell-disease (last visited May 11, 2023).

Medication Utilization by Eligible Individuals with SCD[16]			
Medication	**Patients Eligible for Medication**	**Patients Taking Medication**	**Percent of Eligible Population Taking Medication**
Oral Penicillin	2,054	1,197	58%
Hydroxyurea	7,613	1,691	22%
L-glutamine	6,840	154	2%
Voxelotor	5,629	8	0.1%
Crizanlizumab	4,956	4	0.8%

Medicaid Managed Care Clinical Treatment Programs for SCD

The report identified 72 clinical treatment programs that contract with managed care plans to provide care to individuals with SCD. They include as little as one treatment program offered by a managed care plan to as many as 23, depending on the size and population focus of the plan.[17]

Effect of the Bill

Florida Medicaid Report on Sickle Cell Disease

The bill requires 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 review and report the same information it was required to report by the Fiscal Year 2022-23 GAA. Additionally, it requires AHCA to assess 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, AHCA must assess whether the payment methodologies may be modified or improved.

Sickle Cell Registry

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. 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 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 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 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.

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

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

[16] *Supra* note 2, at 10.
[17] *Supra* note 2, at 17.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None.

2. Expenditures:

The 2023-24 General Appropriations Act (GAA)[18] authorizes the unexpended balance of funds provided to AHCA for the Sickle Cell Disease Medicaid Study by the 2022-23 GAA[19] ($250,000 nonrecurring) to revert for the purpose of conducting the study and report as required by the bill. The bill requires the report to be conducted biannually. If AHCA were to contract for the biannual reports, it would cost $1.25 million every ten years.

The bill also appropriates $1,060,804 in recurring funds, $21,355 in nonrecurring funds, and five full time employee positions, to DOH to implement the SCD registry required by the bill.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

None.

D. FISCAL COMMENTS:

None.

[18] 2023 Florida Legislature, SB 2500 Enrolled, s. 72 (May 5, 2023).
[19] Ch. 2022-156, s. 3, at 189, Laws of Fla.