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 Appropriations

BILL:	SB 7070
INTRODUCER:	Appropriations Committee on Health and Human Services
SUBJECT:	Sickle Cell Disease Research and Treatment Education
DATE:	February 26, 2024
REVISED:	

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
	Gerbrandt	McKnight		**AHS Submitted as Comm. Bill/Fav**
1.	Gerbrandt	Sadberry	AP	**Favorable**

I. Summary:

SB 7070 creates s. 381.814, F.S., establishing the Sickle Cell Disease Research and Treatment Grant Program (Program) with the Florida Department of Health (DOH) to fund projects that improve the quality and accessibility of health care available for persons living with sickle cell disease (SCD) in the state, as well as advance the collection and analysis of comprehensive data to support research of SCD.

The bill defines terms, identifies long-term goals of the Program, and establishes how funds appropriated to the Program may be used for projects specific to SCD. The DOH's Office of Minority Health and Health Equity is responsible for awarding grants to community-based SCD medical treatment and research centers in Florida.

The bill limits the percentage of grant funding used for administrative expenses and authorizes certain appropriated funds to be carried over for a specified timeframe.

The bill lists the duties of the DOH under the Program, requires an annual report with specific information be submitted to the Governor, the President of the Senate, and the Speaker of the House of Representatives, and allows the DOH to adopt rules for Program implementation.

The bill amends s. 383.147, F.S., revising SCD and sickle cell trait screening requirements to require that screening providers notify a newborn's parent or guardian, rather than the newborn's primary care physician, of certain information. The bill also authorizes individuals, other than newborns, that have been identified as having SCD or carrying the sickle cell trait, to volunteer for inclusion on the DOH's sickle cell registry.

The bill creates s. 456.0311, F.S., requiring the applicable health care practitioner regulatory boards for specified health care professions to mandate a two-hour continuing education (CE) course on SCD care management as part of every second biennial licensure or certification

renewal. The bill specifies requirements for the course and the procedure for licensees and certificate holders to submit course completion confirmation.

The bill authorizes applicable boards to approve additional equivalent courses that may be used to satisfy the CE course requirement and to include the course hours in the total hours of CE required for the applicable profession, with an exception. The bill also authorizes health care practitioners holding two or more licenses or certificates subject to the course requirement to show proof of completion of one course to satisfy the requirement for all such licenses or certificates.

The bill provides for disciplinary action and authorizes applicable boards to adopt rules.

The bill may have an indeterminate fiscal impact to the DOH to establish the Program. *See* Section V., Fiscal Impact Statement.

The bill provides an effective date of July 1, 2024.

II. Present Situation:

Florida Department of Health

The Florida Department of Health (DOH) is responsible for the state's public health system, which is designed to promote, protect, and improve the health of all people in the state.[1]

Rare Diseases

The federal Orphan Drug Act defines a rare disease as any condition that nationally affects fewer than 200,000 people. Over 7,000 rare diseases affect more than 30 million people in the U.S. Many rare conditions are life-threatening and most do not have treatments. Drug, biologic, and device development in rare diseases is challenging for many reasons, including the complex biology and the lack of understanding of the natural history of many rare diseases. The inherently small population of patients with a rare disease can also make conducting clinical trials difficult.[2]

Since the Orphan Drug Act was signed into law in 1983, the federal Food and Drug Administration (FDA) has approved hundreds of drugs for rare diseases, but most rare diseases do not have FDA-approved treatments. The FDA works with many people and groups, such as patients, caregivers, and drug and device manufactures, to support rare disease product development. So, while the individual diseases may be rare, the total number of people impacted by a rare disease is larger.[3]

Rare diseases include genetic disorders, infectious diseases, cancers, and various other pediatric and adult conditions. A rare disease can affect anyone at any point in their life, and can be acute

[1] Section 381.001, F.S.
[2] United States Food and Drug Administration, *Rare Diseases at FDA, available at* https://www.fda.gov/patients/rare-diseases-fda (last visited Feb. 16, 2024).
[3] *Id*.

or chronic. It is estimated that 80 percent or more of rare diseases are genetic. For genetic rare diseases, genetic testing is often the only way to make a definitive diagnosis.[4]

Rare diseases present a fundamentally different array of challenges compared to those of more common diseases. Often patients are sent on a "diagnostic odyssey," in order to determine the cause of symptoms, seeking treatment in health care settings unfamiliar with such a rare condition.[5]

Newborn Metabolic Screening Program

The Legislature created the Florida Newborn Screening Program (NBS Program) in 1965 within the DOH to promote the screening of all newborns for metabolic, hereditary, and congenital disorders known to result in significant impairment of health or intellect.[6] The NBS Program also promotes the identification and screening of all newborns in the state and their families for environmental risk factors (i.e., low-income, poor education, maternal and family stress, emotional instability, substance abuse, and other high-risk conditions associated with increased risk of infant mortality and morbidity) to provide early intervention, remediation, and prevention services.[7]

The NBS Program attempts to screen all newborns for hearing impairment and to identify, diagnose, and manage newborns at risk for select disorders that, without detection and treatment, can lead to permanent developmental and physical damage or death.[8] The NBS Program is intended to screen all prenatal women and newborns, however, parents and guardians may choose to decline the screening.[9]

Health care providers perform non-laboratory NBS Program screening, such as hearing and risk factor analysis, and report the results to the Office of Vital Statistics. If necessary, health care providers refer patients to the appropriate health, education, and social services.[10]

Health care providers in hospitals and birthing centers perform specimen collection for laboratory analysis for the NBS Program screening by collecting a few drops of blood from the newborn's heel on a standardized specimen collection card.[11] The specimen card is then sent to the state laboratory for testing and the results are released to the newborn's health care provider.

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[4] Florida Department of Health, *Rare Disease Advisory Council: Legislative Report – Fiscal Year 2022/2023 (2023), available at* https://www.floridahealth.gov/provider-and-partner-resources/rdac/_documents/Rare-Disease-Advisory-Council-Legislative-Report_2023.pdf (last visited Feb. 16, 2024).
[5] Florida Department of Health, *Rare Disease Advisory Council: Legislative Report – Fiscal Year 2022/2023 (2023), available at* https://www.floridahealth.gov/provider-and-partner-resources/rdac/_documents/Rare-Disease-Advisory-Council-Legislative-Report_2023.pdf (last visited Feb. 16, 2024).
[6] Section 383.14(1), F.S.
[7] *Id*.
[8] Florida Department of Health, *Florida Newborn Screening Guidelines, available at* https://floridanewbornscreening.com/wp-content/uploads/NBS-Protocols-2022-FINAL.pdf (last visited Feb. 16, 2024).
[9] Section 383.14(4), F.S.; Fla. Admin. Code R. 64C-7.008, (2023). The health care provider must attempt to get a written statement of objection to be placed in the medical record.
[10] *Id*.
[11] Florida Newborn Screening, *What is Newborn Screening?, available at* https://floridanewbornscreening.com/parents/whatis-newborn-screening/ (last visited Feb. 16, 2024). *See also*, Florida

In the event that a newborn screen has an abnormal result, the newborn's health care practitioner,[12] or a nurse or specialist from the NBS Program's "Follow-up Program," provides follow-up services and referrals for the child and his or her family.[13]

The newborn screening report includes the screening results for all 58 conditions currently screened. Newborn screening is part of the standard of care for all infants. Florida law allows for a parent to opt-out of newborn screening prior to collection. This opt-out is documented in the medical record maintained by the collection facility. The NBS Program maintains the results of the newborn screenings, in addition to diagnostic results for newborns identified with a condition on the screening panel. Data is available from January 2006 forward. The DOH's retention schedule requires newborn screening records to be permanently maintained.[14]

Office of Minority Health and Health Equity

The DOH's Office of Minority Health and Health Equity (Office) was established by the Florida Legislature[15] to administer the Closing the Gap grant program. The Office evaluates and awards grants, determines best practices, and maximizes the benefits of grants.[16]

Closing the Gap Grant Program

The state-funded program, Reducing Racial and Ethnic Health Disparities "Closing the Gap" (CTG) grant[17], supports communities, faith-based entities, and other organizations to eliminate health disparities. CTG grants fund communities to work with partners to improve the health of racial and ethnic populations, eliminate barriers, and achieve optimal health in Florida.

Current priority areas for this grant program include:[18]

- Adult and child immunizations;
- Alzheimer's disease and related dementia;
- Cancer;
- Cardiovascular disease;
- Diabetes;
- HIV/AIDS;

Newborn Screening, *Specimen Collection Card, available at* http://floridanewbornscreening.com/wp-content/uploads/Order-Form.png (last visited Feb. 16, 2024).

[12] Current law allows for the screening results to be released to specified health care practitioners including: allopathic and osteopathic physicians and physician assistants licensed under chs. 458 and 459, F.S., advanced practice registered nurses, registered nurses, and licensed practical nurses licensed under ch. 464, F.S., a midwife licensed under ch. 467, F.S., a speech-language pathologist or audiologist licensed under part I of ch. 468, F.S., or a dietician or nutritionist licensed under part X of ch. 468, F.S.

[13] *Id*.

[14] Department of Health, *2024 Agency Legislative Bill Analysis, SB 1582 (Sept. 18, 2023)* (on file with the Senate Committee on Health Policy).

[15] Section 20.43, F.S.

[16] Florida Department of Health, *Office of Minority Health, available at* https://www.floridahealth.gov/programs-and-services/minority-health/index.html (last visited Feb. 19, 2024).

[17] Section 381.7356, F.S.

[18] Florida Department of Health, *Closing the Gap Grant, available at* https://www.floridahealth.gov/%5C/programs-and-services/minority-health/GrantFundingResources/closing-the-gap.html (last visited Feb. 19, 2024).

- Lupus;
- Maternal and infant mortality;
- Oral healthcare;
- SCD;
- Social determinants of health; and
- Severe maternal morbidity.

Sickle Cell Disease

SCD affects approximately 100,000 Americans and is the most prevalent inherited blood disorder in the U.S.[19] SCD affects mostly, but not exclusively, persons of African ancestry. SCD is a group of inherited disorders in which abnormal hemoglobin cause red blood cells to buckle into a sickle shape. The deformed red blood cells damage blood vessels and over time contribute to a cascade of negative health effects beginning in infancy, such as intense vaso-occlusive pain episodes, strokes, organ failure, and recurrent infections.[20,21] The severity of complications generally worsens with age, but treatment and prevention strategies can mitigate complications and lengthen the lives of those suffering from SCD.[22]

A person who carries a single gene for SCD has the sickle cell trait. Individuals with the sickle cell trait do not have SCD, and under normal conditions they are generally asymptomatic. However, they are carriers of SCD and have an increased likelihood of having a child with SCD. It is estimated that eight to ten percent of African Americans carry the sickle cell trait.[23]

While SCD is the most common inherited blood disorder in the U.S., and is often diagnosed at birth through newborn screening programs,[24] patients with SCD experience many of the other trials associated with treating a rare disease. Until recently there was very little research development in the areas of managing, treating, or curing SCD.[25,26]

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[19] National Institutes of Health, National Heart, Lung, and Blood Institute, *What is Sickle Cell Disease?, available at* https://www.nhlbi.nih.gov/health/sickle-cell-disease (last visited Feb. 16, 2024).
[20] Centers for Disease Control and Prevention, *What is Sickle Cell Disease? available at* https://www.cdc.gov/ncbddd/sicklecell/facts.html (last visited Feb. 16, 2024).
[21] Florida Agency for Health Care Administration, *Florida Medicaid Study of Enrollees with Sickle Cell Disease (2023), available at* https://ahca.myflorida.com/content/download/20771/file/Florida_Medicaid_Study_of_Enrollees_with_Sickle_Cell_Disease.pdf (last visited Feb. 16, 2024).
[22] Centers for Disease Control and Prevention, *Complications of Sickle Cell Disease, available at* https://www.cdc.gov/ncbddd/sicklecell/complications.html (last visited Feb. 16, 2024).
[23] American Society of Hematology, *ASH Position on Sickle Cell Trait (2021), available at* https://www.hematology.org/advocacy/policy-news-statements-testimony-and-correspondence/policy-statements/2021/ashposition-on-sickle-cell-trait (last visited Feb. 16, 2024).
[24] Centers for Disease Control and Prevention, *Newborn Screening (NBS) Data (2023), available at* https://www.cdc.gov/ncbddd/hemoglobinopathies/scdc-state-data/newbornscreening/index.html#:~:text=Newborn%20screening%20(NBS)%20for%20sickle,SCD%20living%20in%20a%20state. (last visited Feb. 16, 2024).
[25] American Society of Hematology, *ASH Sickle Cell Disease Initiative. available at* https://www.hematology.org/advocacy/sickle-cell-disease-initiative (last visited Feb. 17, 2024).
[26] Department of Health, *2024 Agency Legislative Bill Analysis, SB 1582 (Sept. 18, 2023)* (on file with the Senate Committee on Health Policy).

The NBS Program has included screening for SCD since 1988.[27]

Sickle Cell Disease Registry

In 2023, the DOH was required under s. 383.147, F.S., to contract with a community-based SCD medical treatment and research center to establish and maintain a registry for newborns and infants identified as carrying a sickle cell hemoglobin variant. If a screening provider detects that a newborn or an infant is carrying a sickle cell hemoglobin variant, it must notify the child's primary care physician and submit the results to the DOH for inclusion in the sickle cell registry. The registry must track SCD outcome measures. A parent or guardian of a newborn or an infant in the registry may request to have his or her child removed from the registry by submitting a form prescribed by the DOH in rule.[28,29]

Based on a review of the 2022 provisional data, the DOH identified 137 newborns with SCD and 5,800 with the sickle cell trait. For every newborn identified with the sickle cell trait, notification letters were sent to both the family and the physician on file for each newborn. NBS Program results were returned to the submitting provider. It is the responsibility of the submitting entity to forward the results to the newborn's primary care provider.[30,31]

III. Effect of Proposed Changes:

Section 1 creates s. 381.814, F.S., to establish the Sickle Cell Disease Research and Treatment Grant Program (Program) within the Florida Department of Health (DOH), and to define the following terms:

- Center of Excellence – a health care facility dedicated to the treatment of patients with sickle cell disease (SCD), which provides evidence-based, comprehensive, patient-centered coordinated care consistent with criteria established by the DOH.
- Department – the DOH.
- Health care practitioner – the same meaning as provided in s. 456.001(4), F.S.
- Program – the Sickle Cell Disease Research and Treatment Grant Program.
- Sickle cell disease – the group of hereditary blood disorders caused by an abnormal type of hemoglobin resulting in malformed red blood cells with impaired function, including both symptomatic manifestations of SCD and the asymptomatic sickle cell trait.

The bill provides the purpose of the Program, which is to fund projects that improve the quality and accessibility of health care available for persons living with SCD in Florida, as well as to advance the collection and analysis of comprehensive data to support research of SCD. Long-term goals of the Program are as follows:

- Improve the health outcomes and quality of life for Floridians with SCD.
- Expand access to high-quality, specialized care for SCD.

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[27] *Id*.
[28] American Society of Hematology, *ASH Sickle Cell Disease Initiative. available at* https://www.hematology.org/advocacy/sickle-cell-disease-initiative (last visited Feb. 17, 2024).
[29] Department of Health, *2024 Agency Legislative Bill Analysis, SB 1582 (Sept. 18, 2023)* (on file with the Senate Committee on Health Policy).
[30] *Supra* note 28.
[31] *Supra* note 29.

- Improve awareness and understanding among health care practitioners of current best practices for the treatment and management of SCD.

Using funds appropriated for the Program, the bill establishes that the DOH's Office of Minority Health and Health Equity shall award grants to community-based SCD medical treatment and research centers in Florida to fund projects specific to SCD in the following project areas:

- SCD workforce development and education – such projects include, but are not limited to, facility-based education programs, continuing education curriculum development, and outreach and education activities with the local health care practitioner community; workforce development and education projects must be based on current evidence-based clinical practice guidelines for SCD.
- SCD treatment centers of excellence – such projects include, but are not limited to, operational support for existing centers of excellence, facility enhancement of existing centers of excellence, and the establishment of new centers of excellence.
- Surveillance and evaluation – such projects include, but are not limited to, the maintenance of and improvements to an existing SCD and sickle cell trait registry.

The bill provides that a recipient of a grant awarded under the Program may not use more than five percent of grant funds for administrative expenses. Notwithstanding s. 216.301, F.S., and pursuant to s. 216.351, F.S., the bill also allows appropriated Program funds from the General Revenue Fund to be carried forward for up to five years after the effective date of the original appropriation if not disbursed but obligated pursuant to contract or committed to be expended by June 30, of the fiscal year in which the funds are appropriated.

Under the bill, duties of the DOH are as follows:

- Publicize the availability of funds under the Program and establish the application process for submitting a grant proposal.
- Develop uniform data reporting requirements for the purpose of evaluating the performance of the grant recipients and demonstrating improved health outcomes.
- Develop a monitoring process to evaluate progress toward meeting grant objectives.

The bill requires an annual report be submitted to the Governor, the President of the Senate, and the Speaker of the House of Representatives by March 1, of each year. At a minimum, the report must include the status and progress for each project supported by the Program during the previous calendar year, any recommendations for improving the Program, and all of the following components for each supported project:

- A summary of the project and the project outcomes or expected project outcomes.
- The status of the project, including whether it has concluded or the estimated date of completion.
- The amount of the grant awarded and the estimated or actual cost of the project.
- The source and amount of any federal, state, or local government grants or donations or private grants or donations funding the project.
- A list of all entities involved in the project.

The bill provides that the DOH may adopt rules to implement the Program.

Section 2 amends s. 383.147, F.S., to revise SCD and sickle cell trait screening requirements, establishing that a newborn, as defined in s. 383.145(2), F.S., identified as having SCD, or the sickle cell trait, through the NBS Program, as described in s. 383.14, F.S., must:

- Notify the parent or guardian of the newborn and provide information regarding the availability and benefits of genetic counseling; and
- Submit the results of such screening for inclusion in the sickle cell registry, unless the parent or guardian of the newborn provides an opt-out form obtained from the DOH, or otherwise indicates in writing to the DOH his or her objection to having the newborn included in the registry. The DOH must notify such parent or guardian of his or her ability to opt-out.

The bill makes conforming changes to existing statute that provides clarity as to what is meant by hemoglobin variant, striking this language throughout and replacing with SCD or the sickle cell trait. Under this bill, other individuals living in Florida that are identified as having SCD or the sickle cell trait may choose to be included in the sickle cell registry by providing the DOH with notification as prescribed by rule.

Section 3 creates s. 456.0311, F.S., to require the applicable board of each individual licensed or certified under ch. 458, 459, or part I of 464, F.S., to complete a two-hour continuing education (CE) course, approved by the board, on SCD care management as part of very second biennial licensure or certification renewal. The course shall consist of education specific to SCD and the sickle cell trait, including, but not limited to, evidence-based treatment guidelines for patients of all ages, continuing patient and family education, periodic comprehensive evaluations and other disease-specific health maintenance services, psychosocial care, genetic counseling, and pain management.

The bill requires that each licensee or certificate holder submit confirmation of having completed the CE course on a form provided by the applicable board when submitting fees for each second biennial renewal. The applicable board may approve additional equivalent CE courses, and the hours required for completion of the CE course may be included in the total hours of CE required by law for such profession unless the CE requirements consist of fewer than 30 hours biennially.

The bill allows any individual holding two or more licenses, subject to this section, to show proof of having taken one-board approved course to satisfy requirements for purposes of licensure or recertification for additional licenses. Failure to comply with the CE requirements constitutes grounds for disciplinary action under each respective practice act and s. 456.072(1)(k), F.S.

The bill establishes that each applicable board may adopt rules to implement this section.

Section 4 provides an effective date of July 1, 2024.

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:

The bill may have an indeterminate fiscal impact on individuals licensed or certified under ch. 458, 459, or part I of 464, F.S., associated with the cost of the sickle cell disease continuous education course required under the bill.

C. Government Sector Impact:

The bill may have an indeterminate fiscal impact to the Florida Department of Health to establish the Sickle Cell Disease Research and Treatment Grant Program.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill substantially amends section 383.147 of the Florida Statutes.

This bill creates the following sections of the Florida Statutes: 381.814 and 456.031.

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.