A bill to be entitled

An act relating to sickle cell disease; creating s. 383.147, F.S.; requiring a screening provider to notify the primary care physician of newborns and infants if the sickle cell trait is detected and submit the results to the Department of Health for a specified purpose; requiring the primary care physician to provide certain information to the parent or guardian of such newborns and infants; requiring the department to develop and maintain a registry for newborns and infants identified as carrying the sickle cell trait; authorizing a parent or guardian to request the removal of his or her child from the registry by submitting a certain form; requiring the department to establish a system for notifying parents or guardians of children included in the registry of specified information; providing requirements for such notice; requiring the department to provide certain notice and information to persons who are included in the registry and have reached the age of majority; requiring the department to adopt rules; creating s. 385.213, F.S.; requiring the department to collect information and data regarding sickle cell disease and its variants for specified purposes; requiring the department to use such information and data for specified purposes; requiring health care providers to submit information relating to the diagnosis or treatment of patients with sickle cell disease and its variants to the department; specifying such information; requiring health care facilities to make certain records available to the department; requiring the department to publish a report on its website by a specified date and annually; specifying the information and data to be included in such report; requiring the department to adopt rules; creating s. 385.214, F.S.; requiring the department to establish a Sickle Cell Disease Education and Grant Program; providing requirements for such program; requiring the department to award grants to certain organizations approved by the department; requiring the department to develop and implement requirements for grant applications and criteria for awarding grants to approved organizations; authorizing the department to award grants to certain community-based organizations; providing requirements for such organizations; requiring the department to adopt rules; creating s. 409.91191, F.S.; requiring the Agency for Health Care Administration to conduct an annual review of medications, treatments, and services provided for Medicaid recipients diagnosed with sickle cell disease; providing a purpose and requirements for such annual review; requiring the agency to solicit and consider input from the public; requiring the agency to submit a report to the Legislature by a specified date and annually and post such report on its website; creating s. 409.91192, F.S.; requiring the agency to conduct a study regarding innovative sickle cell disease therapies; providing requirements for such study; requiring the agency to hold public hearings; requiring the agency to submit a report to the Governor and Legislature by a specified date; requiring the agency to publish the study on its website; creating s. 409.9751, F.S.; requiring the agency to require Medicaid managed care plans to develop and implement sickle cell disease quality strategy plans; providing requirements for such plans; requiring Medicaid managed care plans to submit their sickle cell disease quality strategy plans to the agency by a specified date; providing duties for the agency; creating ss. 627.64192 and 641.31078, F.S.; defining the term "iatrogenic infertility"; requiring health insurance policies and health maintenance contracts to provide coverage for standard fertility preservation services under certain circumstances; prohibiting health insurers and health maintenance organizations from discriminating against an applicant, policyholder, or subscriber, as applicable, based on certain factors; providing applicability; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. Section 383.147, Florida Statutes, is created to read:

<u>383.147 Newborn and infant screening for sickle cell trait; registry.—</u>

<u>(1) If a screening provider detects that a newborn or infant, as those terms are defined in s. 383.145(2), is carrying the sickle cell trait, it must notify the primary care physician of the newborn or infant and submit the results of such screening to the Department of Health for inclusion in the registry established under paragraph (2)(a). The primary care physician must provide to the parent or guardian of the newborn or infant information regarding the availability and benefits of genetic counseling.</u>

<u>(2)(a) The Department of Health shall develop and maintain a registry for newborns and infants who are identified as carrying the sickle cell trait. A parent or guardian of a newborn or infant may request to have his or her child removed from the registry by submitting a form prescribed by the</u>

department in rule.

(b) The department shall also establish a system for notifying the parents or guardians of children who have been included in the registry that a followup consultation with a physician is recommended. Such notice must be provided to the parents or guardians of such children at least once during early adolescence and once during late adolescence. The department shall make every reasonable effort to notify persons who are 18 years of age and have been included in the registry that they may request to be removed from the registry by submitting a form prescribed by the department in rule. The department shall also provide to such persons information regarding available educational services, genetic counseling, and other beneficial resources.

(3) The Department of Health shall adopt rules to implement this section.

Section 2. Section 385.213, Florida Statutes, is created to read:

385.213 Sickle cell disease; information and data collection; annual report.—

(1)(a) The Department of Health shall collect information and data regarding sickle cell disease and its variants, including, but not limited to, a record of the number patients with sickle cell disease or its variants in the state, for the purposes of enhancing epidemiological research and surveys and evaluating the effectiveness of the various treatments for sickle cell disease and its variants.

(b) The department shall use the information and data it collects pursuant to this section to analyze trends among patients diagnosed with sickle cell disease or its variants, investigate such trends to facilitate and improve the treatment of such patients, and advance research and education relating to sickle cell disease and its variants.

(2)(a) A health care provider who diagnoses or treats a patient with sickle cell disease or a variant of such disease shall submit information relating to such diagnosis or treatment to the Department of Health in a form and manner prescribed by department rule. Such information must include, but need not be limited to, all of the following:

1. A patient's name, address, age, and ethnicity.

2. Whether a patient has been diagnosed with a variant of sickle cell disease.

3. The methods used to treat a patient.

4. Whether a patient has been diagnosed with any other diseases or illnesses.

5. A patient's history of accessing health care services for the treatment of sickle cell disease or a variant of such disease, if known.

6. If a patient has died, his or her age at the time of death.

(b) A health care facility must make available to the department its records relating to each case of sickle cell disease and its variants.

(3) By July 1, 2023, and each year thereafter, the Department of Health shall publish a report based on the information and data collected pursuant to subsection (2) on its website in a manner that is readily accessible to the public. Such annual report must include, but need not be limited to, all of the following information and data:

1. The number of patients diagnosed with sickle cell disease or its variants by county, age, gender, or other demographics.

2. Health care utilization data for all patients diagnosed with sickle cell disease or its variants.

3. Health care utilization data for patients diagnosed with sickle cell disease or its variants who are 60 years of age or older.

4. The number of patients diagnosed with sickle cell disease or its variants who transition from pediatric to adult care upon reaching 18 years of age.

(4) The Department of Health shall adopt rules to implement this section.

Section 3. Section 385.214, Florida Statutes, is created to read:

385.214 Sickle Cell Disease Education and Grant Program.—

(1) The Department of Health shall establish a Sickle Cell Disease Education and Grant Program. The program must include, but is not limited to, all of the following components:

(a) A statewide public education and outreach campaign to promote awareness of evidence-based sickle cell disease screening, detection, and educational services.

(b) Program criteria for awarding grants to organizations approved by the department.

(c) Compilation and dissemination of data relevant to sickle cell disease screening, detection, and treatment.

(d) Development of health care provider education and training programs, including, but not limited to, topics relating to the benefits of early detection of sickle cell disease and clinical examinations, the recommended frequency of clinical examinations and sickle cell disease screenings, and professionally recognized best practices guidelines.

(2)(a) The Department of Health shall award grants to approved organizations that provide services to persons with sickle cell disease and engage in any of the following activities:

1. Promote the early detection of sickle cell disease, including, but not limited to, clinical examinations and screenings;

2. Counsel persons diagnosed with sickle cell disease regarding evidence-based screenings, followup care, and

referrals;

3. Disseminate information regarding sickle cell disease, early detection, and screening to unserved and underserved populations, the general public, and health care providers and facilities;

4. Identify local sickle cell disease screening service providers within the approved organization's region; or

5. Provide information regarding the availability of medical assistance to persons requiring treatment for sickle cell disease.

(b) The department shall develop and implement requirements for grant applications and criteria for awarding grants to approved organizations.

(c) The department may also award grants to community-based organizations that provide postdiagnosis counseling and education and outreach programs for persons diagnosed with sickle cell disease. A community-based organization must provide comprehensive sickle cell disease educational and support services at no cost and must ensure that persons with sickle cell disease are responsible for making decisions regarding their care.

(3) The Department of Health shall adopt rules to implement this section.

Section 4. Section 409.91191, Florida Statutes, is created to read:

409.91191 Medicaid recipients with sickle cell disease; annual review and report.—

(1) The agency shall conduct an annual review of all medications, treatments, and services provided for Medicaid recipients with a diagnosis of sickle cell disease. The purpose of the annual review is to determine if the available covered medications, treatments, and services are adequate to meet the needs of Medicaid recipients with a diagnosis of sickle cell disease and whether the agency should seek federal approval to include additional medications, treatments, or services for coverage under the Medicaid program. In conducting its review, the agency must examine:

(a) The benefits of transferring youth who are transitioning to adulthood to adult care settings.

(b) Whether patients with sickle cell disease receive the equivalent standard of care if referred or transferred to an out-of-state facility.

(c) The extent to which the agency reimburses patients with sickle cell disease for reasonable interstate travel costs.

(d) The extent to which providers in emergency hospital settings are adequately trained and otherwise prepared to treat and manage patients with sickle cell disease who are presenting with vaso-occlusive crises.

(2) The agency shall solicit and consider input from the public, with an emphasis on input from persons or entities with

knowledge and experience in the area of sickle cell disease treatment.

(3) By July 1, 2023, and each July 1 thereafter, the agency shall submit a report containing its findings and recommendations to the Senate President and the Speaker of the House of Representatives and the chairs of the appropriate legislative committees. The agency must post such report on its website in a manner that is readily accessible to the public.

Section 5. Section 409.91192, Florida Statutes, is created to read:

409.91192 Innovative sickle cell disease therapies; study and report.—

(1)(a) The agency shall conduct a study of approaches to reimbursing, covering, and improving access to innovative sickle cell disease therapies which may include, but need not be limited to, separate payments from inpatient bundling, outcomes-based arrangements, carve-outs for costs from managed care, and risk-assuming carriers or reinsurance pools.

(b) The study must include an evaluation of current reimbursement methodologies under the Medicaid program and whether such methodologies restrict access to potentially curative one-time sickle cell disease therapies. The agency must hold at least two public hearings at which stakeholders are to provide input.

(2) By July 1, 2023, the agency shall submit a report to

<u>the Governor, the President of the Senate, and the Speaker of the House of Representatives which contains the agency's findings and recommendations for providing equitable and appropriate access to innovative sickle cell disease therapies. The agency shall publish the complete study on its website in a manner that is readily accessible to the public.</u>

Section 6. Section 409.9751, Florida Statutes, is created to read:

<u>409.9751 Quality care for enrollees with sickle cell disease.—</u>

<u>(1)(a) The agency must ensure that high quality care and services are made available and accessible to enrollees with sickle cell disease. The agency shall require Medicaid managed care plans to develop and implement sickle cell disease quality strategy plans that must include, but are not limited to:</u>

<u>1. Improving the identification of enrollees with sickle cell disease.</u>

<u>2. Ensuring that provider networks are capable of providing adequate and timely access to specialty providers.</u>

<u>3. Implementing care coordination strategies to assist enrollees with sickle cell disease in accessing specialists and other related care supports.</u>

<u>4. Providing training and education for health care providers regarding sickle cell disease, including, but not limited to, topics relating to the emergency warning signs and</u>

<u>complications of sickle cell disease, evidence-based practices and treatment guidelines for sickle cell disease, and providing appropriate referrals to specialty providers.</u>

<u>(b) Each Medicaid managed care plan shall submit its sickle cell disease quality strategy plans to the agency by October 1, 2023.</u>

<u>(2)(a) The agency shall perform all of the following duties:</u>

<u>1. Develop quarterly reports regarding the number of children and adults enrolled in each Medicaid managed care plan who have been identified as having sickle cell disease.</u>

<u>2. In coordination with Medicaid managed care plans, identify, document, and share best practices regarding sickle cell disease care management and coordination with primary care and specialty providers.</u>

<u>3. Enter into partnerships with a postsecondary educational institution to develop a sickle cell disease-focused comprehensive assessment tool to screen enrollees identified with sickle cell disease for various factors relevant to care.</u>

<u>4. Establish performance standards for Medicaid managed care plans which relate to access to care and availability of therapies, patient engagement in treatment, and outcomes for patients with sickle cell disease, with incentive payments for meeting such standards.</u>

<u>5. Develop and implement a plan for improving the</u>

transition of patients from pediatric care to adult care for adolescents with sickle cell disease, including, but not limited to, assisting qualified beneficiaries who may not be eligible for Medicaid coverage due to age to maintain coverage under another eligibility category.

6. Incorporate the performance standards established under subparagraph 4. into Medicaid managed care plan contracts by imposing financial or administrative penalties for failing to meet the performance standards and making adjustments to contracted plan rates.

Section 7. Section 627.64192, Florida Statutes, is created to read:

627.64192 Coverage for fertility preservation services; discrimination prohibited.—

(1)(a) As used in this subsection, the term "iatrogenic infertility" means the impairment of fertility by any medical treatment, including, but not limited to, treatment for sickle cell disease, that affects the reproductive organs or processes.

(b) A health insurance policy issued, amended, delivered, or renewed on or after July 1, 2022, in this state must provide coverage for standard fertility preservation services, including, but not limited to, storage costs, when a necessary medical treatment may directly or indirectly cause iatrogenic infertility to a policyholder.

(2) When determining coverage for fertility preservation

<u>services, a health insurer may not discriminate against an applicant or policyholder based on the applicant's or policyholder's expected length of life, disability, degree of medical dependency, quality of life, other health conditions, or personal characteristics. This subsection does not apply if the United States Department of Health and Human Services issues regulations or guidance requiring the state to defray the cost of coverage for fertility preservation services.</u>

Section 8. Section 641.31078, Florida Statutes, is created to read:

<u>641.31078 Coverage for fertility preservation services; discrimination prohibited.—</u>

<u>(1)(a) As used in this subsection, the term "iatrogenic infertility" means the impairment of fertility by any medical treatment, including, but not limited to, treatment for sickle cell disease, that affects the reproductive organs or processes.</u>

<u>(b) A health maintenance contract issued or renewed on or after July 1, 2022, shall provide coverage for standard fertility preservation services, including, but not limited to, storage costs, when a necessary medical treatment may directly or indirectly cause iatrogenic infertility to a subscriber.</u>

<u>(2) When determining coverage for fertility preservation services, a health maintenance organization may not discriminate against a subscriber based on the subscriber's expected length of life, disability, degree of medical dependency, quality of</u>

life, other health conditions, or personal characteristics. This subsection does not apply if the United States Department of Health and Human Services issues regulations or guidance requiring the state to defray the cost of coverage for fertility preservation services.

Section 9. This act shall take effect July 1, 2022.