By Senator Gibson

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A bill to be entitled

An act relating to sickle-cell disease; amending s. 381.815, F.S.; defining terms; requiring the Department of Health to establish and maintain a sickle-cell registry for a specified purpose; requiring certain providers to report specified information to the registry; requiring the department to use the reported information for specified purposes; requiring the department to analyze the reported information and make certain determinations; requiring the department to publish quarterly reports; providing requirements for the reports; providing duties for the department to promote early detection and treatment of sickle-cell disease; requiring the department to make grants or enter into contracts with certain community-based organizations for the provision of specified services; authorizing the department to adopt rules; amending s. 381.981, F.S.; requiring the department to include sickle-cell disease in its monthly health awareness campaigns; amending s. 383.14, F.S.; requiring the department to adopt rules requiring screening of newborns for sickle-cell disease and sickle-cell trait; requiring any positive test results to be reported to the department’s sickle-cell registry; requiring parents of newborns who test positive to be provided with information on further testing and treatment, as applicable; creating s. 409.9129, F.S.; requiring the Agency for Health Care Administration to require managed care organizations to implement a certain quality strategy for a specified purpose; providing requirements for the strategy; requiring managed care organizations to provide certain quarterly reports to the agency; requiring the agency to coordinate with managed care organizations to identify, document, and share certain best practices and to develop a certain plan; requiring the agency to establish performance measures for managed care organizations; requiring the agency to partner with a publicly funded university to develop an assessment tool for screening enrollees with sickle-cell disease for factors relevant to their care; requiring the agency to incorporate certain standard in its contracts with managed care organizations; requiring the agency to conduct an annual review of the Medicaid program’s coverage of medications, treatments, and services related to sickle-cell disease; providing requirements for the review; requiring the agency to submit a report of its findings and recommendations to the Governor and the Legislature by a specified date and annually thereafter; requiring the agency to publish the report on its website; requiring the agency to conduct a study of innovative approaches for reimbursement for, coverage of, and access to sickle-cell disease therapies; providing requirements for the study; requiring the agency to hold public meetings with relevant stakeholders; requiring the agency to hold its first meeting by a specified date; requiring the agency to prepare a report of its recommendations by a specified date; requiring the agency to submit the report to the Governor and the Legislature and publish it on its website; providing for expiration; creating s. 456.0315, F.S.; requiring certain boards to require their licensees and certificateholders to complete a continuing education course on sickle-cell disease as part of every second biennial license or certification renewal; providing requirements for the course; providing for submission of proof of completion of such course; authorizing the boards to approve additional equivalent courses; authorizing the boards to include such course within already required continuing education hours under certain circumstances; providing an accommodation for individuals who are dually licensed with regard to such courses; providing for discipline; authorizing the boards to adopt rules; creating ss. 627.64055, 627.65741, and 641.31078, F.S.; defining the terms “fertility preservation” and “iatrogenic fertility”; requiring certain individual and group health insurers and health maintenance organizations, respectively, to provide coverage for certain fertility preservation services in connection with medically necessary treatments for sickle-cell disease; prohibiting such insurers and organizations from discriminating in their coverage of such services on the basis of specified factors; providing an effective date.

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

Section 1. Section 381.815, Florida Statutes, is amended to read:

381.815 Sickle-cell program.—

(1) DEFINITIONS.—As used in this section, the term:

(a) “Community-based organization” means an organization in which survivors of sickle-cell disease hold significant decisionmaking responsibilities and which offers evidence-based sickle-cell disease education and support services at no cost to the public.

(b) “Department” means the Department of Health.

(c) “Health care provider” means a health care practitioner as defined in s. 456.001 or a health care facility or other entity licensed or certified to provide health services in this state.

(2) SICKLE-CELL REGISTRY.—The department shall establish and maintain a registry for reporting information on the incidence of sickle-cell disease and its variants in this state and other information for epidemiological surveys and evaluations of treatments.

(a) Health care providers who diagnose or treat patients with sickle-cell disease shall report the following information for each such patient to the department for inclusion in the registry:

1. The patient’s name, address, age, and ethnicity.

2. The variant of sickle-cell disease affecting the patient.

3. The method of treatment used by the provider.

<u>4. Any other diseases the patient may have.</u>

<u>5. The extent to which the patient uses or has access to health care services, if known.</u>

<u>6. If the patient dies, the patient's age at the time of death.</u>

<u>(b)1. Health care providers who conduct newborn screenings for sickle-cell disease and the sickle-cell trait shall report any positive test results to the department for inclusion in the registry in a form and manner prescribed by the department.</u>

<u>2. The department shall develop a notification system that informs parents of newborns entered in the registry under subparagraph 1. of the importance of consulting a physician following a diagnosis of the sickle-cell trait or sickle-cell disease. The department must send such notification immediately following the newborn's registration in the registry and at least once in early childhood and again in later adolescence.</u>

<u>(c) When an individual registered in the registry reaches 18 years of age, the department shall make reasonable efforts to notify the individual of his or her inclusion in the registry and of the availability of educational services, genetic counseling, and other benefits and resources.</u>

<u>(d) The department shall use information reported to the registry to assess trends, advance research and education, and facilitate the improvement of sickle-cell disease treatment in this state. The department shall analyze the data for trends of low usage of or poor access to health care services in particular geographical areas or demographic groups and conduct further investigation to determine whether improvements can be made to facilitate greater access to sickle-cell disease</u>

treatment.

(e) The department shall publish quarterly reports based on information collected in the registry. The reports must include all of the following information:

1. Aggregate data for the general population and for individuals 60 years of age or older which shows the geographical areas, demographics, and health services utilization of individuals with sickle-cell disease or its variants.

2. Data on the transition of adolescents with sickle-cell disease from pediatric care to adult care.

(3) PUBLIC OUTREACH AND SERVICES.—To promote early detection and treatment of sickle-cell disease, the department ~~of Health~~ shall do all of the following~~, to the extent that resources are available~~:

(a)~~(1)~~ Provide statewide education and outreach to inform the public ~~the citizens of Florida~~ about sickle-cell disease, including, but not limited to, available evidence-based sickle-cell screening, detection, and education services.

(b) Develop or approve education and training on sickle-cell disease for health care providers. Such education and training must include, at a minimum, coverage of all of the following:

1. The importance of early detection of sickle-cell disease.

2. Medically appropriate clinical examinations and screening procedures, including the frequency with which they should be provided.

3. Best practices for the detection and treatment of

sickle-cell disease and for emergency treatment and management of patients with sickle-cell disease who present with vaso-occlusive crises.

4. The sickle-cell registry and the reporting requirements established under this section.

(c)~~(2)~~ Work cooperatively with nonprofit organizations ~~not-for-profit centers~~ to provide community-based education, patient teaching, and counseling and to encourage diagnostic screening.

(d)~~(3)~~ Make grants or enter into contracts with nonprofit community-based organizations for provision of the following:

1. Clinical examinations and screenings for sickle-cell disease.

2. Counseling, information on treatment options, and referrals for treatment and services to individuals diagnosed with sickle-cell disease, including information on available economic assistance for treatment.

3. Dissemination of information on sickle-cell disease, early detection, and screening to unserved or underserved populations, the general public, and health care practitioners.

4. Identification of local sickle-cell disease screening services within the organization’s region.

5. Any other services that promote early detection and treatment of sickle-cell disease ~~not-for-profit centers~~.

(4) RULES.—The department may adopt rules to implement this section.

Section 2. Paragraph (v) is added to subsection (2) of section 381.981, Florida Statutes, to read:

381.981 Health awareness campaigns.—

(2) The awareness campaigns shall include the provision of

educational information about preventing, detecting, treating, and curing the following diseases or conditions. Additional diseases and conditions that impact the public health may be added by the board of directors of the Florida Public Health Institute, Inc.; however, each of the following diseases or conditions must be included in an awareness campaign during at least 1 month in any 24-month period:

<u>(v) Sickle-cell disease.</u>

Section 3. Paragraph (a) of subsection (2) of section 383.14, Florida Statutes, is amended to read:

383.14 Screening for metabolic disorders, other hereditary and congenital disorders, and environmental risk factors.—

(2) RULES.—

(a) After consultation with the Genetics and Newborn Screening Advisory Council, the department shall adopt and enforce rules requiring that every newborn in this state shall:

1. Before becoming 1 week of age, be subjected to a test for phenylketonuria;

2. <u>Before becoming 1 week of age, be subjected to a test for sickle-cell disease and the sickle-cell trait. If a newborn tests positive for sickle-cell disease or the sickle-cell trait, the result must be reported to the sickle-cell registry in accordance with s. 381.815 and the parents of the newborn must be given information on further testing and treatment, as applicable;</u>

<u>3.</u> Be tested for any condition included on the federal Recommended Uniform Screening Panel which the council advises the department should be included under the state’s screening program. After the council recommends that a condition be

included, the department shall submit a legislative budget request to seek an appropriation to add testing of the condition to the newborn screening program. The department shall expand statewide screening of newborns to include screening for such conditions within 18 months after the council renders such advice, if a test approved by the United States Food and Drug Administration or a test offered by an alternative vendor is available. If such a test is not available within 18 months after the council makes its recommendation, the department shall implement such screening as soon as a test offered by the United States Food and Drug Administration or by an alternative vendor is available; and

4.~~3.~~ At the appropriate age, be tested for such other metabolic diseases and hereditary or congenital disorders as the department may deem necessary from time to time.

Section 4. Section 409.9129, Florida Statutes, is created to read:

409.9129 Quality assurance in coverage for enrollees with sickle-cell disease.—

(1) QUALITY STRATEGY.—To ensure the availability of accessible, quality health care for enrollees with sickle-cell disease, the agency must require managed care organizations to implement a quality strategy, which must provide for, at a minimum, all of the following:

(a) Improvements in identifying individuals with sickle-cell disease.

(b) An adequate provider network capacity to ensure timely access to specialty providers for sickle-cell disease treatment.

(c) Care coordination strategies to assist enrollees with

<u>sickle-cell disease in accessing specialists and other related care supports.</u>

<u>(d) Delivery of evidence-based training on sickle-cell disease to primary care providers. Such training must include, at a minimum, instruction on warning signs for emergencies and complications, evidence-based practices and treatment guidelines, and appropriate referrals to specialty treatment providers.</u>

<u>(2) QUARTERLY REPORTS; COORDINATION; PERFORMANCE MEASURES.—</u>

<u>(a) Managed care organizations shall provide quarterly reports to the agency which include the number of children and adults with sickle-cell disease enrolled in each plan and any other information the agency deems necessary to achieve the purposes of this section.</u>

<u>(b) The agency, in coordination with the managed care organizations, shall:</u>

<u>1. Identify, document, and share best practices regarding sickle-cell disease care management and coordination with enrolled primary care providers and specialty providers.</u>

<u>2. Develop a plan for transitioning adolescent enrollees with sickle-cell disease from pediatric care to adult care, including, but not limited to, assisting enrollees who may age out of the Medicaid program to maintain Medicaid coverage under another eligibility category, if qualified.</u>

<u>(c) The agency shall establish performance measures for managed care organizations relating to access to care and available therapies for sickle-cell disease, engagement in treatment, and outcomes for enrollees with sickle-cell disease. The agency may use financial incentives to encourage compliance</u>

with the performance measures.

(3) ASSESSMENT TOOL.—The agency shall partner with a publicly funded university to develop a comprehensive sickle-cell disease assessment tool to screen enrollees with sickle-cell disease for factors relevant to their care.

(4) CONTRACTS.—The agency shall incorporate standards for coverage of sickle-cell disease treatment in its contracts with managed care organizations, including financial or administrative penalties for noncompliance and adjustments to contracted plan rates to reflect enhanced care.

(5) ANNUAL REVIEW.—The agency shall conduct an annual review of the Medicaid program's coverage of medications, treatments, and services for enrollees diagnosed with sickle-cell disease.

(a) In its review, the agency shall do all of the following:

1. Review all covered medications, treatments, and services to determine whether such coverage is adequate for the effective treatment of individuals diagnosed with sickle-cell disease and whether the agency should seek Medicaid coverage for additional medications, treatments, or services.

2. Review Medicaid coverage of out-of-state treatment of enrollees with sickle-cell disease, comparing it with coverage for similar in-state treatment, to determine whether the program ensures coverage for an equivalent standard of care for patients who are referred or transferred to an out-of-state provider for treatment.

3. Determine the extent to which Medicaid reimburses sickle-cell patients for reasonable interstate travel costs

associated with treatment for sickle-cell disease.

4. Review Medicaid coverage of treatment for emerging adults with sickle-cell disease as they transition into the adult care setting.

5. Determine the extent to which emergency room physicians are adequately trained and prepared to treat and manage patients with sickle-cell disease who present with vaso-occlusive crises.

6. Solicit and consider input from the public, including individuals impacted by sickle-cell disease and individuals or groups with knowledge or experience in sickle-cell disease treatment.

(b) By January 15, 2023, and by January 15 of each year thereafter, the agency shall submit a report of its findings and recommendations to the Governor, the President of the Senate, and the Speaker of the House of Representatives. The agency shall also publish the report on its website.

(6) STUDY OF INNOVATIVE PAYMENT MODELS TO ENHANCE ACCESS TO SICKLE-CELL DISEASE THERAPIES.—

(a) The agency shall conduct a study of innovative approaches to reimbursement for, coverage of, and access to sickle-cell disease therapies, including, but not limited to, separate payments from inpatient bundling, outcomes-based arrangements, carving out sickle-cell disease treatment costs from managed care, and risk-sharing or reinsurance pools. The study must, at a minimum, assess whether current reimbursement methodologies restrict access to potentially curative one-time sickle-cell disease therapies.

(b) The agency shall hold at least two public meetings providing an opportunity for public comments and involving discussions between the agency; health care providers who screen for, diagnose, or treat sickle-cell disease; community-based organizations that serve individuals diagnosed with sickle-cell disease; survivors of sickle-cell disease; and other relevant stakeholders. The agency must hold its first meeting by September 1, 2022.

(c) By November 1, 2023, the agency shall prepare a report of its final recommendations for policies to be implemented by the agency to support equitable and appropriate access to innovative sickle-cell disease therapies and recommendations for any legislation required to allow the agency to implement such policies. The agency shall submit its report to the Governor, the President of the Senate, and the Speaker of the House of Representatives and publish the report on its website.

(d) This subsection expires on December 1, 2023.

Section 5. Section 456.0315, Florida Statutes, is created to read:

456.0315 Requirement for instruction on sickle-cell disease.—

(1)(a) The appropriate board shall require each person licensed under chapter 458, chapter 459, part I of chapter 464, or chapter 467 to complete, as part of every second biennial license or certification renewal, a 1-hour continuing education course, approved by the board, on sickle-cell disease. The course must cover at least all of the following:

1. The importance of early detection of sickle-cell disease.

2. Medically appropriate clinical examinations and screening procedures, including the frequency with which they

should be provided.

3. Best practices for the detection and treatment of sickle-cell disease and for emergency treatment and management of patients with sickle-cell disease who present with vaso-occlusive crises.

4. The sickle-cell registry and related reporting requirements established under s. 381.815.

(b) Each licensee or certificateholder must submit confirmation of having completed the course on a form provided by the board when submitting fees for every second biennial license or certification renewal.

(c) The board may approve additional equivalent courses that may be used to satisfy the requirements of paragraph (a), including the education and training developed or approved by the department under s. 381.815(3)(b). Each licensing board that requires a licensee to complete an educational course pursuant to this subsection may include the hour required for completion of the course in the total hours of continuing education required by law for such profession unless the continuing education requirements for such profession consist of fewer than 30 hours biennially.

(2) Any person holding two or more licenses or certifications subject to this section may show proof of having taken one board-approved course on sickle-cell disease, for purposes of renewing such additional licenses or certifications.

(3) Failure to comply with this section constitutes grounds for disciplinary action under the chapters specified in paragraph (1)(a) and s. 456.072(1)(k). In addition to any discipline imposed by the board, the licensee also must be

required to complete the required course.

(4) Each applicable board may adopt rules to implement this section.

Section 6. Section 627.64055, Florida Statutes, is created to read:

627.64055 Coverage for fertility preservation services.—

(1) As used in this section, the term:

(a) “Fertility preservation” means the process by which a person’s eggs, sperm, or reproductive tissue is saved or protected for future attempts at conception.

(b) “Iatrogenic infertility” means an impairment of fertility which is caused by a medical treatment that affects reproductive organs or processes.

(2) A health insurance policy issued, delivered, or renewed in this state on or after July 1, 2022, which provides coverage for medically necessary treatments for sickle-cell disease must also provide coverage for fertility preservation services, including storage costs, if a medically necessary treatment for sickle-cell disease may directly or indirectly cause iatrogenic infertility of the insured.

(3) In its coverage of fertility preservation services under this section, an insurer may not discriminate on the basis of the insured’s life expectancy, disability, degree of medical dependency, quality of life, or other health conditions or personal characteristics.

Section 7. Section 627.65741, Florida Statutes, is created to read:

627.65741 Coverage for fertility preservation services.—

(1) As used in this section, the term:

(a) “Fertility preservation” means the process by which a person’s eggs, sperm, or reproductive tissue is saved or protected for future attempts at conception.

(b) “Iatrogenic infertility” means an impairment of fertility which is caused by a medical treatment that affects reproductive organs or processes.

(2) A group health insurance policy issued, delivered, or renewed in this state on or after July 1, 2022, which provides coverage for medically necessary treatments for sickle-cell disease must also provide coverage for fertility preservation services, including storage costs, if a medically necessary treatment for sickle-cell disease may directly or indirectly cause iatrogenic infertility of the insured.

(3) In its coverage of fertility preservation services under this section, an insurer may not discriminate on the basis of the insured’s life expectancy, disability, degree of medical dependency, quality of life, or other health conditions or personal characteristics.

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

641.31078 Coverage for fertility preservation services.—

(1) As used in this section, the term:

(a) “Fertility preservation” means the process by which a person’s eggs, sperm, or reproductive tissue is saved or protected for future attempts at conception.

(b) “Iatrogenic infertility” means an impairment of fertility which is caused by a medical treatment that affects reproductive organs or processes.

(2) A health maintenance contract issued or renewed in this

state on or after July 1, 2022, which provides coverage for medically necessary treatments for sickle-cell disease must also provide coverage for fertility preservation services, including storage costs, if a medically necessary treatment for sickle-cell disease may directly or indirectly cause iatrogenic infertility of the subscriber.

(3) In its coverage of fertility preservation services under this section, a health maintenance organization may not discriminate on the basis of the subscriber’s life expectancy, disability, degree of medical dependency, quality of life, or other health conditions or personal characteristics.

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