By Senator Burton

12-01277B-25 20251356__

A bill to be entitled

An act relating to the Florida Institute for Pediatric Rare Diseases; creating s. 1004.4210, F.S.; establishing the Florida Institute for Pediatric Rare Diseases within the Florida State University College of Medicine; providing the goals of the institute; requiring the institute to establish and administer the Sunshine Genetics Pilot Program for a specified period; providing the purpose of the pilot program; providing institute responsibilities and duties relating to the pilot program; providing requirements for participation in the pilot program and data collection in the pilot program; providing reporting requirements for the pilot program; establishing the Sunshine Genetics Consortium for specified purposes; requiring the consortium to be administered at the institute by a board; providing for the membership and terms of the board; providing reporting requirements for the consortium; providing appropriations; providing an effective date.

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

Section 1. Section 1004.4210, Florida Statutes, is created to read:

<u>1004.4210 The Florida Institute for Pediatric Rare Diseases; the Sunshine Genetics Pilot Program; the Sunshine Genetics Consortium.—</u>

<u>(1) The Florida Institute for Pediatric Rare Diseases is</u>

established within the Florida State University College of Medicine as a statewide resource for pediatric rare disease research and clinical care. The purpose of the institute is to improve the quality of life and health outcomes for children and families affected by rare diseases by advancing knowledge, diagnosis, and treatment of pediatric rare diseases through research, clinical care, education, and advocacy.

(2) The goals of the institute are to:

(a) Conduct research to better understand the causes, mechanisms, and potential treatments for pediatric rare diseases, including leveraging emerging research methods.

(b) Develop advanced diagnostic and genetic screening tools and techniques to enable health care providers to identify rare diseases in newborns and children more rapidly, accurately, and economically.

(c) Provide comprehensive multidisciplinary clinical services and care for children with rare diseases. Such care may include patient, family, and caregiver support and resources to help navigate the challenges associated with these conditions, support groups, and patient advocacy.

(d) Educate and train health care professionals, including genetic counselors, pediatricians, scientists, and other specialists in the field of pediatric rare diseases.

(e) Establish collaborations with other research institutions, medical centers, and government agencies whenever deemed appropriate by the institute director and to share expertise, raise awareness, and promote a collective effort to tackle pediatric rare diseases.

(3)(a) The institute shall establish and administer the

Sunshine Genetics Pilot Program to be administered for a period of 3 years. The pilot program shall offer genetic testing to newborns in addition to the state’s newborn screening program.

(b) The institute shall partner with qualified state universities, colleges, and health care service providers to implement the pilot program and deliver and analyze genetic testing results for the pilot program.

(c) The pilot program shall be an opt-in program and a parent of a newborn must provide parental consent to join the pilot program.

(d) Upon the completion of the genetic testing through the pilot program, all testing data and reports shall be delivered to the parent’s health care provider.

(e) The institute shall:

1. Conduct the pilot program in accordance with the requirements of s. 760.40.

2. Maintain a secure database to store all pilot program data, including newborn testing data.

3. Deidentify all patient data.

4. Upon the approval of the board of the Sunshine Genetics Consortium created under subsection (4), enter into an agreement with the consortium to share deidentified patient data.

(f) Upon the completion of the pilot program, the institute shall provide a report to the Governor, the President of the Senate, and the Speaker of the House of Representatives.

(4)(a) The Sunshine Genetics Consortium is established to create a network of clinical and academic research professionals, geneticists, and physicians from state universities and the state’s children’s hospitals to collaborate with leaders in the genetic industry and build and support a culture of collaborative research and the development of cutting-edge genetic and precision medicine in the state. The consortium shall:

1. Integrate state-of-the-art genomic sequencing technologies.

2. Create a biorepository network and database for ongoing and future research.

3. Leverage advancements in artificial intelligence utilization in genomics.

4. Develop educational opportunities for clinicians on genomic tools.

5. Support the growth and education of geneticists to meet demand.

6. Raise funds from nonprofits, private industry, and others to expand the pilot program under subsection (3).

7. Promote patient care to support families with children diagnosed with genetic disorders.

(b)1. The consortium shall be administered at the institute by an oversight board and shall meet periodically.

2. The oversight board for the consortium shall serve 2-year terms and consist of the following voting members:

a. One member from the Florida State University to be appointed by the Dean of the College of Medicine.

b. One member from the University of Florida to be appointed by the Dean of the College of Medicine.

c. One member from the University of South Florida to be appointed by the Dean of the College of Medicine.

d. One member from the University of Miami to be appointed by the Dean of the College of Medicine.

e. One member appointed by the Governor.

f. One member appointed by the President of the Senate.

g. One member appointed by the Speaker of the House of Representatives.

3. The board shall be responsible for the technical performance and financial management of the consortium.

(c) The consortium shall annually provide a report to the Governor, the President of the Senate, and the Speaker of the House of Representatives.

Section 2. For the 2025-2026 fiscal year, the sum of $5 million in recurring funds is appropriated from the General Revenue Fund to the Florida Institute for Pediatric Rare Diseases.

Section 3. For the 2025-2026 fiscal year, the sum of $20 million in nonrecurring funds is appropriated from the General Revenue Fund to the Florida Institute for Pediatric Rare Diseases to launch and execute whole genome sequencing at birthing centers.

Section 4. This act shall take effect July 1, 2025.