FLORIDA HOUSE OF REPRESENTATIVES
BILL ANALYSIS

This bill analysis was prepared by nonpartisan committee staff and does not constitute an official statement of legislative intent.

BILL #: CS/CS/HB 907	**COMPANION BILL:** CS/SB 1356 (Burton)
TITLE: Florida Institute for Pediatric Rare Diseases	**LINKED BILLS:** None
SPONSOR(S): Anderson	**RELATED BILLS:** None

Committee References

Education Administration	➤	Health & Human Services	➤	Health Care Budget	➤	Education & Employment
17 Y, 0 N, As CS		25 Y, 0 N		14 Y, 0 N, As CS		

SUMMARY

Effect of the Bill:

The bill codifies the Florida Institute for Pediatric Rare Diseases (Institute) within the Florida State University College of Medicine as a statewide resource for research and clinical care related to pediatric rare diseases. The Institute will conduct research, develop diagnostic and genetic screening tools, provide multidisciplinary clinical services and care, educate and train healthcare professionals, and collaborate with other institutions and organizations.

The bill requires the Institute to establish and administer the Sunshine Genetics Pilot Program (pilot program) for 5 years, offering opt-in newborn genetic screening, to include whole genome sequencing, with parental consent. Any clinical findings from the screening must be released to the parents and newborn's healthcare practitioner. The Institute must maintain a secure database of pilot program data and provide deidentified data for research.

The bill also establishes the Sunshine Genetics Consortium (Consortium) to facilitate collaboration among researchers, geneticists, and physicians from Florida's state universities and children's hospitals. Overseen by an oversight board, the Consortium will build and support research and development of cutting edge genetic and precision medicine in the state.

Fiscal or Economic Impact:

The implementation of the bill is contingent on the availability of funding provided in the General Appropriations Act for such purpose.

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ANALYSIS

EFFECT OF THE BILL:

Florida Institute for Pediatric Rare Diseases

The bill codifies the Florida Institute for Pediatric Rare Diseases (Institute) 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. (Section 1)

The bill specifies that the goals of the Institute are to:

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

- Provide comprehensive multidisciplinary clinical services and care for children with rare diseases. Such care may include, but is not limited to, patient, family, and caregiver support and resources to help navigate the challenges associated with these conditions, support groups, and patient advocacy.
- Educate and train health care professionals, including, but not limited to, genetic counselors, pediatricians, scientists, and other specialists in the field of pediatric rare diseases.
- Establish collaborations with other research institutions, medical centers, patient and family advocacy organizations, and government agencies whenever deemed appropriate by the Institute director to share expertise, raise awareness, and promote a collective effort to tackle pediatric rare diseases.

The bill requires the Institute to establish and administer the Sunshine Genetics Pilot Program (pilot program) for a period of 5 years. The pilot program must provide newborn genetic screening, including, but not limited to, whole genome sequencing. Genetic screening will be performed by the Institute and institutional members of the oversight board upon approval of the oversight board.

The bill authorizes the Institute to establish partnerships with Florida universities and colleges and health care service providers to promote and assist in the implementation of the pilot program.

The bill requires a parent of a newborn to provide consent to participate in the pilot program.

The Institute and institutional members of the oversight board must release clinical findings of a newborn's screening to the newborn's health care practitioner and the newborn's parent. The bill defines "health care practitioner" to include:

- a physician or physician assistant licensed under chapter 458;
- an osteopathic physician or physician assistant licensed under chapter 459;
- an advanced practice registered nurse, registered nurse, or licensed practical nurse licensed under part I of chapter 464;
- a midwife licensed under chapter 467;
- a speech-language pathologist or audiologist licensed under part I of chapter 468;
- a dietitian or nutritionist licensed under part X of chapter 468; or
- a genetic counselor licensed under part III of chapter 483.

The bill requires the Institute to:

- Maintain a secure database to collect and store all pilot program data, including, but not limited to, newborn genomics sequence data and deidentified newborn data.
- Provide deidentified newborn data to members of the consortium pursuant to a data sharing agreement to support ongoing and future research.

Additionally, by December 1, 2030, the Institute is required to provide a report to the Governor, the President of the Senate, and the Speaker of the House of Representatives on the pilot program, including, at a minimum:

- Study population and enrollment metrics.
- Whole genome sequencing metrics.
- Clinical and public health impact.
- Cost effectiveness and economic benefits.

Sunshine Genetics Consortium

The bill establishes the Sunshine Genetics Consortium (Consortium) 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. (Section 1) The Consortium must:

- Integrate state-of-the-art genomic sequencing technologies.
- Advance research and the development of cutting edge genetic and precision medicine.
- Leverage advancements in artificial intelligence utilization in genomics.
- Develop educational opportunities for clinicians on genomic tools.
- Support the growth and education of geneticists to meet demand.

- Solicit and leverage funds from nonprofits, private industry, and others for the purpose of expanding the pilot program and to support genetic screenings by institutional members of the oversight board.
- Promote patient care that supports families with children diagnosed with genetic disorders.
- Report on the use of deidentified newborn data by members of the consortium.

The bill establishes an oversight board to administer the Consortium at the Institute, consisting of:

- the director of the Institute, who serve as the chair, and the following voting members who must serve 2-year terms:
    - One member nominated by the dean of the University of Florida's College of Medicine and approved by the university's president.
    - One member nominated by the dean of the University of South Florida's College of Medicine and approved by the university's president.
    - One member nominated by the dean of the University of Miami's School of Medicine and approved by the university's president.
    - One member nominated by the dean of Florida International University's School of Medicine and approved by the university's president.
    - One member nominated by the Nicklaus Children's Hospital and approved by the hospital's president and chief executive officer.
    - One member appointed by the Governor.
    - One member appointed by the President of the Senate.
    - One member appointed by the Speaker of the House of Representatives.

The board must convene at least once every 6 months and its members are responsible for the promotion and oversight of the consortium, including, but not limited to, the nomination and appointment of members of the Consortium.

The bill requires the Consortium, beginning October 15, 2026, and annually thereafter, to provide a report to the Governor, the President of the Senate, and the Speaker of the House of Representatives on research projects, research findings, community outreach initiatives, and future plans for the Consortium. (Section 1).

The effective date of the bill is July 1, 2025. (Section 2).

FISCAL OR ECONOMIC IMPACT:

STATE GOVERNMENT:

The implementation of the bill is contingent on the availability of funding provided in the General Appropriations Act for such purpose. (Section 1)

RELEVANT INFORMATION

SUBJECT OVERVIEW:

Rare Diseases

In the United States, a rare disease is any condition that nationally affects fewer than 200,000 people. There may be as many as 10,000 rare diseases impacting the lives of 30 million Americans and their families.[1] So, while the individual diseases may be rare, the total number of people impacted by a rare disease is large.

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 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

[1] National Organization for Rare Diseases (NORD), NORD *Rare Disease Database*, https://rarediseases.org/rare-diseases/ (last visited Mar. 6, 2025).

to make a definitive diagnosis. Rare diseases present a fundamentally different array of challenges compared to those of more common diseases; often patients are set on a "diagnostic odyssey," in order to determine the cause of their symptoms as they seek treatment in health care settings where their condition may have never been seen before.[2]

The Andrew John Anderson Pediatric Rare Disease Grant Program

In 2024, the Florida Legislature established the Andrew John Anderson Pediatric Rare Disease Grant Program (Grant Program) within the Department of Health to support research on pediatric rare diseases. The Grant Program awards grants through a competitive, peer-reviewed process to advance new diagnostics, treatments, and cures.[3]

DOH, in consultation with the Rare Diseases Advisory Council,[4] awards grants to universities and established research institutes in Florida for scientific and clinical research. Preference may be given to proposals that foster collaborations among institutions, researchers, and community practitioners.[5]

In both 2023 and 2024, the Legislature appropriated $500,000 for the Grant Program.[6]

Florida State University Institute for Pediatric Rare Diseases

In 2024, Florida State University (FSU) established the Institute for Pediatric Rare Diseases (Institute) at the FSU College of Medicine. It is the mission of the Institute to transform the lives of children affected by rare diseases through research, education, diagnosis, and clinical care.[7]

The goals include:[8]

- Harnessing interdisciplinary collaboration by bringing together scientists, clinicians, and educators to address the challenges of pediatric rare diseases.
- Leveraging advancements in gene therapy and immune response research to improve treatment outcomes.
- Enhancing the quality of life for the 15 million children across the United States affected by pediatric rare diseases.

In 2023, the Legislature allocated $1,000,000 to the Institute,[9] and another $5,000,000 in 2024.[10]

Newborn Screening Program

The Legislature created the Florida Newborn Screening Program (NSP) within DOH, to promote the screening of all newborns for metabolic, hereditary, and congenital disorders known to result in significant impairment of health or intellect.[11] The NSP also promotes the identification and screening of all newborns in the state and their families for environmental risk factors such as 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.[12]

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[2] Department of Health, *Rare Disease Advisory Council: Legislative Report, Fiscal Year 2023-2024* (2024), at 6-7, *available at* https://www.floridahealth.gov/provider-and-partner-resources/rdac/_documents/2024-rdac-annual-report.pdf, (last visited March 28, 2025).

[3] S. 381.991(1)(a), F.S., *see also* Ch. 224-246, L.O.F.

[4] See S. 381.99, F.S. The Rare Disease Advisory Council is created adjunct to the DOH for the purpose of providing recommendations on ways to improve health outcomes for individuals residing in this state who have a rare disease.

[5] S. 381.991(1)(b) – (2)(a), F.S. *See also,* Florida Health*, Rare Pediatric Diseases Research Grant Program,* https://www.floridahealth.gov/provider-and-partner-resources/research/research-programs1/RarePediatricDiseasesResearchGrantProgram.html, (last visited March 28, 2025).

[6] Specific Appropriation 539A, s. 3, Ch. 2023-239, L.O.F. and Specific Appropriation 546A, s. 3, Ch. 2024-231, L.O.F.

[7] Florida State University, *Florida State University News, FSU launches groundbreaking Institute for Pediatric Rare Diseases*, https://news.fsu.edu/news/health-medicine/2024/02/01/fsu-launches-groundbreaking-institute-for-pediatric-rare-diseases/; *see also*, Florida State University, *Institute for Pediatric Rare Diseases*, https://med.fsu.edu/iprd/home (last visited March 28, 2025).

[8] *Id*.

[9] Specific Appropriation 143, s. 2, Ch. 2023-239, L.O.F.

[10] Specific Appropriation 147, s. 2, Ch. 2024-231, L.O.F.

[11] S. 383.14(1), F.S.

[12] S. 383.148(1), F.S.

The NSP 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.[13] The NSP is intended to screen all prenatal women and newborns, however, parents and guardians may choose to decline the screening.[14]

Newborn screenings are completed after the baby is 24 hours of age and before discharge from the hospital. For births outside a hospital setting, the birth provider either completes the screening or arranges for testing within 1-2 days after birth.[15]

The Florida Genetics and Newborn Screening Advisory Council advises DOH on disorders to be included in the NSP panel of screened disorders and the procedures for collecting and transmitting specimens.[16] Florida's NSP currently screens for 58 conditions, 55 of which are screened through the collection of blood spots.[17] Health care providers collect drops of blood from the newborn's heel on a standardized specimen collection card which is then sent to the state laboratory for testing.[18]

If necessary, health care providers refer patients to the appropriate health, education, and social services.[19] Screening results are released to the newborn's health care provider; in the event of an abnormal result, the baby's health care provider, or a nurse or specialist from NSP's Follow-up Program provides follow-up services and referrals for the child and his or her family.[20]

RECENT LEGISLATION:

YEAR	BILL #	HOUSE SPONSOR(S)	SENATE SPONSOR	OTHER INFORMATION
2024	CS/CS/CS/SB 1582	Anderson	Rodriguez	The Andrew John Anderson Pediatric Rare Disease Grant Program became effective on July 1, 2024.

OTHER RESOURCES:

National Organization for Rare Disorders (NORD)

[13] Florida Department of Health, *Florida Newborn Screening 2022 Guidelines*, *available at* https://floridanewbornscreening.com/wp-content/uploads/NBS-Protocols-2022-FINAL.pdf. See also, Florida Newborn Screening, https://floridanewbornscreening.com/ (last visited March 28, 2025).
[14] S. 383.14(4), F.S.; Rule 64C-7.008, F.A.C.; The hospital provider shall request any parent or guardian who objects to infant (postnatal) risk screening of their child or ward, after the purpose of the screening has been fully explained, to indicate the objection in writing on the electronic birth record risk screening instrument.
[15] Florida Newborn Screening, *What is Newborn Screening*, https://floridanewbornscreening.com/parents/what-is-newborn-screening/ (last visited March 28, 2025).
[16] S. 383.14(6)(a), F.S.
[17] Department of Health, *Agency Analysis of 2024 HB 1441*.
[18] Florida Newborn Screening Program, *What is Newborn Screening? available at* https://floridanewbornscreening.com/parents/what-is-newborn-screening/ (last visited March 28, 2025). *See also,* Florida Newborn Screening, *Specimen Collection Card*, http://floridanewbornscreening.com/wp-content/uploads/Order-Form.png (last visited March 28, 2025).
[19] *Id*.
[20] Department of Health, *Agency Analysis of 2024 HB 1441.*

BILL HISTORY

COMMITTEE REFERENCE	ACTION	DATE	STAFF DIRECTOR/ POLICY CHIEF	ANALYSIS PREPARED BY
Education Administration Subcommittee	17 Y, 0 N, As CS	3/11/2025	Sleap	Dixon
THE CHANGES ADOPTED BY THE COMMITTEE:	• Extended the duration of the Sunshine Genetics Pilot Program (pilot program) from 3 years to 5 years. • Required genetic screening to be performed by the Institute of Pediatric Rare Diseases (institute) and institutional members of the Sunshine Genetics Consortium (consortium) oversight board, subject to the board's approval. • Authorized, rather than required, the institute to establish partnerships with various entities to promote and assist with implementation of the pilot program. • Provided definitions for the term health care practitioner and clarified that clinical findings of a newborn's screening must be delivered to both the newborn's parent and health care practitioner. • Revised the requirement of data stored and shared by the institute. • Revised the institute's reporting requirements on the pilot program specifying that, by December 1, 2030, the institute must provide a report to include an overview of key metrics and the program's impact on health, cost-effectiveness, and economic benefits. • Removed the requirement for the consortium to create a biorepository network. • Expanded the consortium's responsibilities to include advancing genetic research and precision medicine, soliciting funding to expand the pilot program, and the genetic screening by oversight board institutions. • Specified meeting requirements for the consortium's oversight board. • Modified the selection process for university-approved members of the consortium oversight board. • Revised the oversight board's responsibilities from financial and technical management to general promotion and oversight of the consortium.			
Health & Human Services Committee	25 Y, 0 N	3/24/2025	Calamas	McElroy
Health Care Budget Subcommittee	14 Y, 0 N, As CS	4/1/2025	Clark	Smith
THE CHANGES ADOPTED BY THE COMMITTEE:	• Added one member from the Florida International University School of Medicine and one member from the Nicklaus Children's Hospital to the Consortium oversight board. • Removes appropriations from the bill. • Specifies the implementation of the bill is contingent on an appropriation provided in the General Appropriations Act for such purpose.			
Education & Employment Committee				

THIS BILL ANALYSIS HAS BEEN UPDATED TO INCORPORATE ALL OF THE CHANGES DESCRIBED ABOVE.
