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 Appropriations Committee on Health and Human Services

BILL:	CS/SB 1582
INTRODUCER:	Health Policy Committee and Senator Rodriguez
SUBJECT:	Department of Health
DATE:	February 19, 2024 REVISED:

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Rossitto-Van Winkle	Brown	HP	**Fav/CS**
2.	Gerbrandt	McKnight	AHS	**Pre-meeting**
3.			FP	

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/SB 1582 amends numerous statutory provisions relating to the Department of Health (DOH) and creates a new program within the department. The bill:

- Creates a new profession, the environmental health technician (EHT), and allows the technician to perform septic tank inspections without having a four-year degree;
- Creates the Andrew John Anderson Pediatric Rare Disease Grant Program to advance research and cures for rare pediatric diseases by awarding grants through a competitive, peer-reviewed process;
- Clarifies the responsibility for providing newborn screenings and the submission of newborn screening specimen cards. The bill also adds genetic counselors to the list of health care practitioners who may receive state lab results;
- Standardizes the requirements for newborn, infant, and toddler hearing screening at hospitals, licensed birth facilities, and birth centers to ensure timely congenital cytomegalovirus (CMV) screening;
- Allows parents or guardians of newborns who have been identified as having sickle cell disease or carrying the sickle cell trait to opt-out of the state's sickle cell registry; and
- Standardizes requirements, and clarifies the purpose, of prenatal high-risk pregnancy and postnatal infant mortality and morbidity screening for environmental risk factors.

The bill does not have a fiscal impact on state expenditures. See Section V., Fiscal Impact Statement.

The bill takes effect July 1, 2024.

II. Present Situation:

The Department of Health

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

Environmental Health Professionals

Environmental health is that segment of public health work that deals with the examination of those factors in the human environment which may adversely impact the health status of an individual or the public.[2] An environmental health professional (EHP) is a person employed or assigned the responsibility of assessing the environmental health or sanitary conditions, as defined by the DOH, within a building, on an individual's property, or within the community at large, and who has the knowledge, skills, and abilities to carry out these tasks. An EHP may be a field, supervisory, or administrative staff member.[3]

A person may not perform environmental health or sanitary evaluations in any primary program area of environmental health without being certified by the DOH as competent to perform such evaluations, with several exceptions.[4] Those exceptions include:

- Persons performing inspections of public food service establishments licensed under ch. 509, F.S., or
- Persons performing site evaluations to determine proper placement and installation of onsite wastewater treatment and disposal systems who have completed a DOH-approved soils morphology course and who are working under the direct responsible charge of an engineer licensed under ch. 471, F.S.

A person seeking certification as an EHP in any primary program area must:[5]

- Be employed or assigned to provide environmental health services in any primary environmental health program;[6]
- Submit the application and application fee to the DOH for the primary environmental health program in which the applicant seeks certification; and
- Submit an official college transcript evidencing a bachelor's degree from an accredited college or university with major coursework in environmental health, environmental science, or physical or biological science.

[1] Section 381.001, F.S.
[2] Section 381.010,(1)(c), F.S.
[3] Section 381.010,(1)(d), F.S.
[4] Section 381.010,(2), F.S. This section does not apply to persons performing inspections of public food service establishments licensed under ch. 509, F.S.; or persons performing site evaluations in order to determine proper placement and installation of onsite wastewater treatment and disposal systems who have successfully completed a DOH-approved soils morphology course and who are working under the direct responsible charge of an engineer licensed under ch. 471, F.S.
[5] Fla. Admin. Code R. 64E-18.003(2023).
[6] Section 381.0101(2), F.S.

Within 45 days of the DOH's receipt of the completed application, the applicant will receive notice of whether he or she meets the general requirements and is eligible for certification and if eligible, will receive a schedule for classes and program examinations.

Applicants seeking certification in the Onsite Sewage Treatment and Disposal System Program must:

- Complete 24 hours of the DOH-provided pre-certification coursework which includes training and testing on soil classification, system design and theory, system material and construction standards, and regulatory requirements; and
- Pass the examinations administered by the DOH with a minimum passing score of 70 percent.[7]

Applicants seeking certification in the Food Protection Program must:

- Complete 24 hours of the DOH-provided pre-certification coursework which includes training and testing on food microbiology, foodborne illness investigations, and basic hazard analysis and critical control points (HACCP); and
- Pass the pre-certification coursework and certification examinations administered by the DOH with a minimum passing score of 70 percent.[8]

The DOH currently employs 448 certified environmental health professionals (CEHP), most of whom are housed in county health departments (CHD) to perform health evaluations at public food establishments and sanitary evaluations on private and business properties where onsite wastewater treatment and disposal systems are in use. Other CEHPs supervise CHD environmental health teams or work within the Bureau of Environmental Public Health to direct statewide programs.[9]

Section 381.0065, F.S., gives the Department of Environmental Protection (DEP) authority to inspect onsite sewage treatment and disposal systems (OSTDS), which CHD staff complete for the DEP as outlined in a five-year interagency agreement required by Section 2 of Chapter 2020-150, Laws of Florida. It also authorizes four groups to complete private provider septic inspections, including two that do not require a four-year degree.[10]

Section 381.0101(4), F.S., sets out the standards for certification and grants the DOH the authority to adopt rules that establish definitions of terms and minimum standards of education, training, or experience for those seeking certification. CEHPs must earn certification from the DOH to perform evaluations of environmental or sanitary conditions in any program area of environmental health. However, due to the four-year degree requirement for environmental health professionals under section 381.0101(4)(e), F.S., CHDs are experiencing a shortage of qualified applicants for the OSTDS and food hygiene programs.[11]

[7] Fla. Admin. Code R. 64E-18.003(6)(2023).
[8] Fla. Admin. Code R. 64E-18.003(7)(2023).
[9] This excludes establishments licensed under ch. 509, F.S., which operate under separate standards. *See*, Department of Health, 2024 Agency Legislative Bill Analysis, SB 1582 (Sept. 18, 2023) (on file with the Senate Committee on Health Policy).
[10] Department of Health, 2024 Agency Legislative Bill Analysis, SB 1582 (Sept. 18, 2023) (on file with the Senate Committee on Health Policy).
[11] *Id.*

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 United States. 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.

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 manufacturers, 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.[12]

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 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," to determine the cause of their symptoms as they seek treatment in healthcare settings where their condition may have never been seen before.[13]

Rare Pediatric Disease (RPD) Designation and Voucher Programs

Under Section 529 of the Federal Food, Drug, and Cosmetic Act (FD&C Act), the FDA will award priority review vouchers to sponsors of rare pediatric disease product applications that meet certain criteria. Under this program, a sponsor who receives approval for a drug or biologic for a "rare pediatric disease" may qualify for a voucher that can be redeemed to receive a priority review of a subsequent marketing application for a different product.[14]

On December 27, 2020, the Rare Pediatric Disease Priority Review Voucher Program was extended. Under the current statutory sunset provisions, after September 30, 2024, the FDA may only award a voucher for an approved rare pediatric disease product application if the sponsor has a rare pediatric disease designation for the drug and that designation was granted by

[12] United States Food and Drug Administration, *Rare Diseases at FDA*, available at https://www.fda.gov/patients/rare-diseases-fda (last visited Jan. 31, 2024).
[13] 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/RDACLegislativeReport2023Final_Draft.pdf (last visited Jan. 31, 2024).
[14] United States Food and Drug Administration, *Rare Pediatric Disease (RPD) Designation and Voucher Programs*, available at https://www.fda.gov/industry/medical-products-rare-diseases-and-conditions/rare-pediatric-disease-rpd-designation-and-voucher-programs (last visited Jan. 31, 2024).

September 30, 2024. After September 30, 2026, the FDA may not award any rare pediatric disease priority review vouchers.[15]

Rare Disease Advisory Council

In June 2021, the Rare Disease Advisory Council (Council) was created as an adjunct to the DOH. The Council comprises representatives from state agencies, health care providers, researchers, advocacy groups, insurance, and pharmaceutical industries, as well as individuals with rare diseases and caregivers of individuals with rare diseases. Council members hold a shared vision: to improve health outcomes for individuals residing in Florida who have rare diseases. The Council reports annually to the Governor, Senate President, and Speaker of the House of Representatives[16] The DOH is responsible for four research grant programs and will implement the proven strategies and processes for awarding highly meritorious grants that will support advancements for the prevention, treatment, and cures of pediatric rare diseases.[17]

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.[18] The NBS Program 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.[19]

The Legislature established the Florida Genetics and Newborn Screening Advisory Council to advise the DOH on disorders to be included in the NBS Program panel of screened disorders and the procedures for collecting and transmitting specimens.[20] The NBS Program began with the screening for phenylketonuria and now screens for 58 conditions prior to discharge. Of the conditions screened, 55 conditions are screened through the collection of blood spots. Screening of the three remaining conditions – hearing (hearing screening), critical congenital heart defect (CCHD) (pulse oximetry), and congenital cytomegalovirus (CMV) targeted screening – are completed at the birthing facility through point of care (POC) testing.[21]

The NBS Program involves coordination across several entities, including the Bureau of Public Health Laboratories Newborn Screening Laboratory in Jacksonville (state laboratory), The DOH

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[15] United States Food and Drug Administration, *Rare Pediatric Disease (RPD) Designation and Voucher Programs*, available at https://www.fda.gov/industry/medical-products-rare-diseases-and-conditions/rare-pediatric-disease-rpd-designation-and-voucher-programs (last visited Jan. 31, 2024).
[16] Section 381.99, F.S.
[17] 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/RDACLegislativeReport2023Final_Draft.pdf (last visited Jan. 31, 2024).
[18] Section 383.14(1), F.S.
[19] *Id*.
[20] Section 383.14(5), F.S.
[21] Department of Health, 2024 Agency Legislative Bill Analysis, SB 1582 (Sept. 18, 2023) (on file with the Senate Committee on Health Policy).

Children's Medical Services (CMS) Newborn Screening Follow-up Program in Tallahassee, referral centers, birthing centers, and physicians throughout the state.[22] Healthcare providers in hospitals, birthing centers, perinatal centers, county health departments, and school health programs provide screening as part of the multilevel NBS Program screening process.[23] This includes a risk assessment for prenatal women, risk factor analysis and screening for postnatal women and newborns, and laboratory screening for select disorders in newborns.[24] 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.[25] The NBS Program is intended to screen all prenatal women and newborns, however, parents and guardians may choose to decline the screening.[26]

Healthcare 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, healthcare providers refer patients to the appropriate health, education, and social services.[27]

Healthcare 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. [28] The specimen card is then sent to the state laboratory for testing and the results are released to the newborn's health care provider. If a newborn screen has an abnormal result, the newborn's health care practitioner,[29] 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.[30]

To administer the NBS Program, the DOH is authorized to charge and collect a fee, not to exceed $15 per live birth, occurring in a hospital or birth center.[31] The DOH must calculate the annual assessment for each hospital and birth center, and then quarterly generate and mail each hospital and birth center a statement of the amount due.[32] The DOH bills hospitals and birth centers quarterly using vital statistics data to determine the amount to be billed.[33] The DOH is

[22] Section 383.14, F.S.
[23] Section 383.14, F.S.
[24] *Id*.
[25] Florida Department of Health, *Florida Newborn Screening Guidelines, a*vailable at https://floridanewbornscreening.com/wp-content/uploads/NBS-Protocols-2022-FINAL.pdf (last visited Jan. 31, 2024).
[26] 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.
[27] *Id*.
[28] Florida Newborn Screening, *What is Newborn Screening?* available at https://floridanewbornscreening.com/parents/what-is-newborn-screening/ (last visited Jan. 31, 2024). *See also,* Florida Newborn Screening, *Specimen Collection Card,* available at http://floridanewbornscreening.com/wp-content/uploads/Order-Form.png (last visited Jan. 31, 2024).
[29] 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.
[30] *Id*.
[31] Section 383.145(3)(g)1., F.S.
[32] *Id*.
[33] Section 383.145(3)(g), F.S.

authorized to bill third-party payers for the NBS Program tests and bills insurers directly for the cost of the screening.[34] The DOH does not bill families that do not have insurance coverage.[35]

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 and diagnostic results for newborns identified with a condition on the screening panel. Data are available from January 2006 forward. The DOH's retention schedule requires newborn screening records to be permanently maintained.[36]

Newborn Hearing Screening

Section 383.145, F.S., requires newborn hearing screening for all newborns in hospitals before discharge. The newborn hearing screening program (NBHS) is housed within the DOH, which coordinates the statewide hearing screening and follow-up referral system. The NBHS program is funded through a donations trust and federal grants from the federal Centers for Disease Control and Prevention and the Health Resources and Services Administration (HRSA).[37]

Before a newborn is discharged from a hospital or other state-licensed birthing facility, and unless objected to by the parent or legal guardian, the newborn must be screened for the detection of hearing loss to prevent the consequences of unidentified disorders.[38] For births occurring in a non-hospital setting, specifically a licensed birth center or private home, the facility or attending health care provider is responsible for providing a referral to an audiologist, a hospital, or other newborn hearing screening provider within seven days after the birth or discharge from the facility.[39]

All screenings must be conducted by a licensed audiologist, a licensed physician, or appropriately supervised individual who has completed documented training specifically for newborn hearing screening.[40] When ordered by the treating physician, screening of a newborn's hearing must include auditory brainstem responses, evoked otoacoustic emissions, or appropriate technology as approved by the FDA.[41]

NBHS staff provide follow-up to parents of infants who do not pass the newborn hearing screen to ensure timely diagnosis and enrollment in early intervention for children diagnosed with hearing loss.[42] A child who is diagnosed as having a permanent hearing impairment must be referred by the licensee or individual who conducted the screening to the primary care physician

[34] Section 383.145(3)(h), F.S.
[35] Section 383.14, F.S.
[36] Department of Health, 2024 Agency Legislative Bill Analysis, SB 1582 (Sept. 18, 2023) (on file with the Senate Committee on Health Policy).
[37] *Id*.
[38] Section 383.145(3), F.S. If the screening is not completed before discharge due to scheduling or temporary staffing limitations, the screening must be completed within 21 days after the birth.
[39] Section 383.145(3)(d), F.S.
[40] Section 383.145(3)(f), F.S.
[41] Section 383.145(3)(i), F.S.
[42] Section 383.14, F.S.

for medical management, treatment, and follow-up services. Furthermore, any child from birth to 36 months of age who is diagnosed as having a hearing impairment that requires ongoing special hearing services must be referred to the Children's Medical Services Early Intervention Program by the licensee or individual who conducted the screening serving the geographical area in which the child resides.

Hearing loss is one of the most common birth defects in the U.S., with approximately two newborns per 1,000 born having hearing loss each year. It is estimated that only half of early childhood hearing loss is detected through newborn hearing screening. To further support early identification of hearing loss prior to school entry to prevent the consequences of unidentified disorders, the federal Health Resources & Services Administration grants also require collection of hearing screening data for infants and toddlers up to age 36 months.[43]

Sickle Cell Disease

Sickle cell disease (SCD) affects approximately 100,000 Americans and is the most prevalent inherited blood disorder in the U.S.[44] 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.[45] The severity of complications generally worsens as people age, but treatment and prevention strategies can mitigate complications and lengthen the lives of people with SCD.[46]

A person who carries a single gene for SCD has sickle cell trait. People with 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 sickle cell trait.[47]

While SCD is the most common inherited blood disorder in the U.S., and is often diagnosed at birth through newborn screening programs,[48] patients with SCD experience many of the other

[43] Section 383.14, F.S.
[44] 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 Jan. 31, 2024).
[45] Centers for Disease Control and Prevention, *What is Sickle Cell Disease?* available at https://www.cdc.gov/ncbddd/sicklecell/facts.html (last visited Jan. 31, 2024). See also, AHCA (2023) *Florida Medicaid Study of Enrollees with Sickle Cell Disease*. available at https://ahca.myflorida.com/content/download/20771/file/Florida_Medicaid_Study_of_Enrollees_with_Sickle_Cell_Disease.pdf (last visited Jan., 2024).
[46] Centers for Disease Control and Prevention, *Complications of Sickle Cell Disease*. available at https://www.cdc.gov/ncbddd/sicklecell/complications.html (last visited Jan. 31, 2024).
[47] 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/ash-position-on-sickle-cell-trait (last visited Jan. 31, 2024).
[48] Centers for Disease Control and Prevention. *Newborn Screening (NBS) Data* (2023). available at https://www.cdc.gov/ncbddd/hemoglobinopathies/scdc-state-data/newborn-screening/index.html#:~:text=Newborn%20screening%20(NBS)%20for%20sickle,SCD%20living%20in%20a%20state. (last visited Jan. 31, 2024).

trials associated with treating a rare disease. Until recently there was very little research development in the areas of managing, treating, or curing SCD.[49]

The NBS Program has included screening for sickle cell disease since 1988.

Sickle Cell Disease Registry

In 2023, the DOH was required under s. 383.147, F.S., to contract with a community-based sickle cell disease medical treatment and research center to establish and maintain a registry for newborns and infants who are 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 sickle cell disease 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.

Based on a review of the 2022 provisional data, the DOH identified 137 newborns with SCD and 5,800 with sickle cell trait. For any newborn identified with sickle cell trait, notification letters are sent to both the family and physician on file for each newborn. NBS Program results are returned to the submitting provider. It is the responsibility of the submitting entity to forward the results to the newborn's primary care provider.[50]

Environmental Risk Screening

In 2022, 223,833 women gave birth in Florida.[51] Adverse birth outcomes, such as preterm birth and low birthweight, are major public health concerns due to the associated risks of morbidity and mortality throughout an individual's lifespan.[52,53] Risk assessment in pregnancy can assist with identifying pregnant women who are most likely to experience adverse health events and enables providers to administer risk-appropriate prenatal and postnatal care.[54] Research has also shown that the use of risk screening tools significantly reduces the risk of low birth weight, preterm birth, and fetal and infant morbidity.[55] Some researchers have found that the risk of low

[49] *See*, American Society of Hematology. *ASH Sickle Cell Disease Initiative*. available at https://www.hematology.org/advocacy/sickle-cell-disease-initiative (last visited Jan. 31, 2024). See also Department of Health, 2024 Agency Legislative Bill Analysis, SB 1582 (Sept. 18, 2023) (on file with the Senate Committee on Health Policy).
[50] *Id.*
[51] FloridaHealthCHARTS: *Resident Live Births*, available at https://www.flhealthcharts.gov/ChartsDashboards/rdPage.aspx?rdReport=BirthMonthly.Dataviewer&cid=25 (last visited Feb. 1, 2024).
[52] Risnes KR, Vatten LJ, Baker JL, et al..*Birthweight and mortality in adulthood: A systematic review and meta-analysis, Int J Epidemiol* 2011;40:647–661, available at https://pubmed.ncbi.nlm.nih.gov/21324938/ (last visited Feb. 1, 2024).
[53] Raju TNK, Pemberton VL, Saigal S, et al.. *Long-Term Healthcare Outcomes Of Preterm Birth: An Executive Summary of a Conference Sponsored By The National Institutes of Health*. *J Pediatr* 2017;181:309–318.e1. available at https://pubmed.ncbi.nlm.nih.gov/27806833/ (last visited Feb. 1, 2024).
[54] Board on Children, Youth, and Families; Institute of Medicine; National Research Council. (2013). An Update on Research Issues in the Assessment of Birth Settings. *Workshop Summary. Washington (DC): National Academies Press (US)*., available at https://www.ncbi.nlm.nih.gov/books/NBK201935/ (last visited Feb. 1, 2024).
[55] Department of Health, 2024 Agency Legislative Bill Analysis, SB 1582 (Sept. 18, 2023) (on file with the Senate Committee on Health Policy).

birth weight and preterm birth is reduced by as much as thirty percent in underserved communities when a risk screen is completed.[56]

The DOH develops and oversees the prenatal risk screening process to assess for environmental risk factors that put a pregnant woman at risk for a preterm birth or other high-risk condition. The prenatal risk screen is completed by the pregnant woman's healthcare provider at her first prenatal appointment. If the prenatal risk screen identifies a pregnant woman is at-risk, she is referred to home visiting services, and other services, as necessary, to improve prenatal and birth outcomes.

III. Effect of Proposed Changes:

Section 1. Environmental Health Professionals

The bill amends s. 381.0101, F.S., to create a new profession, the environmental health technician (EHT). The bill provides that an EHT is a person employed or assigned the responsibility for conducting septic inspections under the supervision of a certified environmental health professional (CEHP). An EHT must have completed training approved by the DOH and have the knowledge, skills, and abilities to carry out these tasks.

The bill also creates an additional exemption to the certification requirements in s. 381.010(2), F.S., which require a bachelor's degree in science for EHTs employed by a department[57] who are assigned the responsibility of conducting septic tank inspections under the supervision of a CEHP in onsite sewage treatment and disposal.

The bill requires:

- The Department of Health (DOH), in conjunction with the Department of Environmental Protection (DEP), to adopt rules that establish definitions and minimum standards of education, training, and experience for the certification of EHTs, and the rules must address the following:
  - Education required;
  - Training required;
  - Experience necessary;
  - Application process;
  - Examinations to be taken;
  - Process of certification issuance;
  - Certification expiration;
  - Certification renewal; and
  - Ethical standards of practice for the profession.
- The DOH to establish standards for an EHT in the areas of onsite sewage treatment and disposal;
- A person conducting septic inspections must be certified by examination to be knowledgeable in the area of onsite sewage treatment and disposal;

[56] Department of Health, 2024 Agency Legislative Bill Analysis, SB 1582 (Sept. 18, 2023) (on file with the Senate Committee on Health Policy).
[57] Section 20.03(8), F.S., defines "department" as the principal administrative unit within the executive branch of state government.

- An applicant for certification as an EHT to have received a high school diploma or its equivalent;
- An applicant for certification as an EHT to be employed by a department;
- An applicant for certification as an EHT to complete supervised field inspection work as prescribed by DOH rule before examination;
- A certified environmental health technician (CEHT) to renew his or her certification biennially by completing at least 24 contact hours of continuing education for each program area in which he or she maintains certification, subject to a maximum of 48 hours for multi-program certification; and
- A CEHT to notify the DOH within 60 days after any change of name or address from that which appears on the current certificate.

According to the DOH, an EHT could perform septic inspections, like a CEHP, but the technician would not be required to have a four-year college degree with certain scientific coursework to be eligible for this certification examination. Technicians would be required to complete an amount of observed field work set by rule, attain a passing score on the certification test, and meet any additional rule requirements. Regulatory work would include approving permits, and the technician's work would be subject to the supervision and approval of his or her supervising CEHP.[58]

Section 2. Andrew John Anderson Pediatric Rare Disease Grant Program

The bill creates the Andrew John Anderson Rare Pediatric Disease Grant Program within the DOH under s. 381.991, F.S. The purpose of the grant program is to advance the progress of research and cures for rare pediatric diseases by awarding grants through a competitive, peer-reviewed process. Subject to an annual appropriation by the Legislature, the program must award grants for scientific and clinical research to further the search for new diagnostics, treatments, and cures for rare pediatric diseases.

The bill requires that:

- Applications for the grants may be submitted by any university or established research institute in Florida and all qualified investigators, regardless of institutional affiliation, will have equal access and opportunity to compete for funding;
- The grants may be awarded by the DOH after consultation with the Rare Disease Advisory Council based on scientific merit, as determined by the competitive, peer-reviewed process to ensure objectivity, consistency, and high quality;
- The DOH must appoint peer review panels of independent, scientifically qualified individuals to review the scientific merit of each proposal and establish its priority score to ensure appropriate and fair evaluation of grant applications based on scientific merit;
- The priority scores must be forwarded to the council and must be considered in determining which proposals will be recommended for funding; and
- The council and the peer review panels must establish and follow rigorous guidelines for ethical conduct and adhere to a strict policy about conflicts of interest.

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

The bill authorizes:

- The use of preferences for grant proposals that foster collaboration among institutions, researchers, and community practitioners, on the basis that such proposals support the advancement of treatments and cures for rare pediatric diseases through basic or applied research;
- The following types of applications to be considered for funding:
  - Investigator-initiated research grants;
  - Institutional research grants; and
  - Collaborative research grants, including those that advance the finding of treatment and cures through basic or applied research.
- The balance of any Legislative appropriation for the Grant Program that is not disbursed, but is obligated pursuant to contract or committed to be expended by June 30 of the fiscal year in which the funds were appropriated, to be carried forward for up to five years after the effective date of the original appropriation.

The bill prohibits any council or panel member from participating in any discussion or decision of the council or panel concerning a research proposal by any firm, entity, or agency that the member is associated with as a member of the governing body or as an employee or with which the member has entered into a contractual arrangement.

Section 3. Newborn Metabolic Screening Program

The bill amends s. 383.14, F.S., to require that any health care practitioner present at a birth or responsible for primary care during the neonatal period has the primary responsibility of administering newborn screenings as required in ss. 383.14 and 383.145, F.S. The bill defines the term "health care practitioner" to mean physicians or physician assistants (PAs) licensed under ch. 458, F.S., or ch. 459, F.S., advanced practice registered nurses (APRNs) licensed under ch. 464, F.S, and a midwife licensed under ch. 467, F.S., and requires those practitioners to prepare and send all newborn screening specimen cards to the State Public Health Laboratory.

The bill removes language related to risk screening for environmental risk factors from s. 383.14, F.S., and relocates it to s. 383.148, F.S., later in the bill (Section 6). The bill also repeals the following:

- Obsolete requirement for the Office of Inspector General to certify financial operations of the NBS program;
- Obsolete requirement for the NBS Program and Healthy Start to coordinate with the Florida Department of Education (DOE) for consultation; and
- Language referencing the initial newborn screening condition (phenylketonuria) and multiple other screening methods to allow the NBS Program to apply principles to all conditions on the NBS Program screening panel.

The bill authorizes:

- Licensed genetic counselors to receive NBS Program results, which will improve the coordination of services provided to infants and their families; and
- The NBS Program to implement systemic improvements for diagnostic reporting and submission of NBS Program specimens and point of contact screening results.

Section 4. Newborn Hearing Screening

The bill amends s. 383,145, F.S., to add the definition of "toddler" to mean a child from 12 months to 36 months of age. The bill requires that:

- Both infants and toddlers are added to the hearing screening program when a treating physician orders a hearing screening which must include auditory brainstem responses, or evoked otoacoustic emissions, or appropriate technology as approved by the FDA;
- All licensed birth centers that provide maternity and newborn care services must ensure that all newborns are, before discharge, screened for the detection of hearing loss and that within seven days after the birth, the licensed birth center must ensure that all newborns who do not pass the hearing screening are referred for an appointment for a test to screen for congenital cytomegalovirus (CMV) before the newborn becomes 21 days of age; and
- For home births, the newborn's primary health care provider must refer the newborn for administration of a test approved by the FDA or another diagnostically equivalent test on the newborn to screen for congenital CMV before the newborn becomes 21 days of age.

Section 5 Sickle Cell Disease Registry

The bill amends s. 383.147, F.S., to provide that:

- If a newborn is identified as having sickle cell disease or carrying a sickle cell trait through the NBS Program, the results will be included in the statewide SCD registry unless the parent or guardian provides an opt-out form obtained from the DOH, or otherwise indicates in writing of his or her objection to having the newborn included in the registry; and
- Persons living in this state who have been identified as having sickle cell disease or carrying a sickle cell trait may choose to be included in the registry by providing the DOH with notification as prescribed by rule.

Section 6. Environmental Risk Screening

The bill creates s. 383.148, F.S., to house the DOH's requirements relating to screening pregnant women and infants in this state for environmental risk factors, which are being relocated from s. 383.14, F.S.

The bill also amends ss. 383.318, 395.1053, and 456.0496, F.S., to make conforming cross-reference changes.

The bill 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:

None.

C. Government Sector Impact:

According to the Department of Health, the bill does not have a fiscal impact on state expenditures. The Pediatric Rare Disease Research Grant Program is currently funded at $500,000. This funding is used exclusively for research grants. To ensure the proper evaluation of the research grants, the bill requires peer reviewers.

VI. Technical Deficiencies:

None.

VII. Related Issues:

A child's sickle cell disease (SCD) test results are required to be automatically included in the statewide SCD registry under current law. On lines 667-683, the bill allows a parent or guardian to opt-out of having a child's SCD test results included in the registry by submitting an opt-out form "obtained from the department" or by otherwise indicating in writing to the Department of Health of his or her objections to having the child included in the registry. However, there is no requirement in the opt-out procedure created by the bill for the parent or guardian to be informed of the existence of the opt-out form or of his or her ability to opt-out.

VIII. Statutes Affected:

This bill substantially amends the following sections of the Florida Statutes: 381.0101, 383.14, 383.145, 383.147, 383.318, 395.1053, and 456.0496.

This bill creates the following sections of the Florida Statutes: 381.991 and 383.148.

IX. Additional Information:

A. Committee Substitute – Statement of Substantial Changes:
(Summarizing differences between the Committee Substitute and the prior version of the bill.)

CS by Health Policy on February 6, 2024:
The committee substitute removes the Telehealth Minority Maternity Care Program from the bill.

B. Amendments:

None.

This Senate Bill Analysis does not reflect the intent or official position of the bill's introducer or the Florida Senate.