HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: CS/HB 1441 Department of Health
SPONSOR(S): Health Care Appropriations Subcommittee, Anderson
TIED BILLS: **IDEN./SIM. BILLS:** SB 1582

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Healthcare Regulation Subcommittee	19 Y, 0 N	Osborne	McElroy
2) Health Care Appropriations Subcommittee	14 Y, 0 N, As CS	Aderibigbe	Clark
3) Health & Human Services Committee			

SUMMARY ANALYSIS

HB 1441 makes changes to several programs administered under the Department of Health (DOH).

Environmental health professionals (EHPs) are certified by DOH to perform evaluations of environmental or sanitary conditions in two environmental health program areas: food hygiene and onsite sewage treatment and disposal. The bill creates an environmental health technician certification for candidates to work under the supervision of a certified EHP.

The Legislature established the Rare Disease Advisory Council (RDAC) in 2021 to assist DOH in providing recommendations to improve health outcomes for individuals with rare diseases residing in the state. In the United States, a rare disease is any condition that nationally affects fewer than 200,000 people. There may be as many as 7,000 rare diseases impacting the lives of 25-30 million Americans and their families. The bill creates the Andrew John Anderson Pediatric Rare Disease Grant Program within DOH with the purpose of advancing the progress of research and cures for rare pediatric diseases through the award of grants by a competitive, peer-reviewed process. Grants shall be awarded by DOH, after consultation with the RDAC.

Sickle cell disease is a rare disease affecting approximately 100,000 Americans. In 2023, the Legislature directed DOH to partner with a community-based sickle cell disease medical treatment and research center to establish and maintain a registry to track outcome measures of newborns who are identified as carrying a sickle cell hemoglobin variant. The bill revises certain requirements for the registry related to who may be included in the registry, and the process by which parents can opt their newborns out of the registry.

The Florida Newborn Screening Program (NSP) promotes the screening of all newborns for metabolic, hereditary, and congenital disorders known to result in significant impairment of health or intellect. The NSP also promotes the identification and screening of all newborns in the state and their families for environmental risk factors. The bill revises the certain aspects of the NSP to specify the responsibilities of relevant health care practitioners and repeal obsolete provisions.

Newborns are also required to undergo hearing screening before they are discharged from the hospital. The bill standardizes hearing screening practices for newborns born in licensed birth facilities and requires screening results for children up to 36 months of age be reported to DOH.

The bill has an insignificant, negative fiscal impact on DOH, which current resources are adequate to absorb.

The bill has no fiscal impact on local governments.

The bill provides an effective date of July 1, 2024.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Environmental Health Professionals

Current Situation

Environmental health professionals (EHPs) are certified by the Department of Health (DOH) to perform evaluations of environmental or sanitary conditions in two environmental health program areas: food hygiene and onsite sewage treatment and disposal.[1]

DOH currently employs 448 certified EHPs, most of which are housed in county health departments 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.[2]

EHPs must be certified by DOH to perform evaluations of environmental or sanitary conditions in food hygiene or onsite sewage treatment and disposal. Current law requires an EHP to have graduated from an accredited four-year college or university with a degree or major coursework in public health, environmental health, environmental science, or a physical or biological science to be certified.[3] According to DOH, county health departments are experiencing a shortage of qualified applicants to the food hygiene and onsite sewage treatment and disposal programs due to the requirement for a four-year degree.[4]

In 2020, the Legislature transferred the Onsite Sewage Program from DOH to the Department of Environmental Protection (DEP). In establishing the transfer, the Legislature also required that the agencies enter into an interagency agreement for a period of no less than five years in order to coordinate the logistics relating to collaboration with the county health departments and the transfer or shared use of buildings or facilities owned by DOH.[5]

Effect of Proposed Changes – Environmental Health Professionals

The bill creates a certification for environmental health technicians who will be authorized to conduct septic tank inspections under the supervision of an environmental health professional who is certified in onsite sewage treatment and disposal.

The bill directs DOH, in conjunction with DEP, to adopt rules to establish standards for environmental health technicians, as well as, relevant administrative processes. To obtain and maintain certification as an environmental health technician, one must:

- Be certified by examination to be knowledgeable in the area of onsite sewage treatment and disposal;
- Have a high school diploma, or its equivalent;
- Be employed by a department as defined in s. 20.03;
- Complete supervised field inspection work as prescribed by rule before examination;
- Renew certification biennially by completing at least 24 contact hours of continuing education; and
- Notify the department within 60 days after any change of name or address.

[1] S. 381.0101(4), F.S.
[2] This excludes establishments licensed under Ch. 509, F.S., which operate under separate standards. *See*, Department of Health, *Agency Analysis of HB 1441* (2024). On file with the Healthcare Regulation Subcommittee.
[3] S. 381.0101(4)(e), F.S.
[4] *Supra*, note 2.
[5] Ch. 2020-150, L.O.F.

Rare Diseases

Current Situation

In the United States, a rare disease is any condition that nationally affects fewer than 200,000 people. There may be as many as 7,000 rare diseases impacting the lives of 25-30 million Americans and their families.[6] 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 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.[7]

In 2023, the Legislature allocated $500,000 in General Revenue funds in the General Appropriations Act for pediatric rare disease research grants.[8]

Rare Disease Advisory Council

The Legislature established the Rare Disease Advisory Council (RDAC) in 2021 to assist DOH in providing recommendations to improve health outcomes for individuals with rare diseases residing in the state.[9]

The establishment of RDACs across the country is an initiative spearheaded by the National Organization for Rare Disorders (NORD),[10] a national nonprofit group advocating for individuals and families affected by rare diseases.[11] Florida was the 19th state to establish a RDAC through legislation.[12]

Florida's RDAC is directed to:[13]

- Consult with experts on rare diseases and solicit public comment to assist in developing recommendations on improving the treatment of rare diseases in Florida;
- Develop recommended strategies for academic research institutions in Florida to facilitate continued research on rare diseases;
- Develop recommended strategies for health care providers to be informed on how to more efficiently recognize and diagnose rare diseases in order to effectively treat patients; and
- Provide input and feedback in writing to DOH, the Medicaid program, and other state agencies on matters that affect people who have been diagnosed with rare diseases.

Rare Disease Registries – Sickle Cell Disease

[6] National Organization for Rare Diseases, *Rare Disease Day: Frequently Asked Questions*. Available at https://rarediseases.org/wp-content/uploads/2019/01/RDD-FAQ-2019.pdf (last visited January 19, 2024).
[7] 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 January 20, 2024).
[8] Ch. 2023-239, L.O.F., line item 539A; *See also*, Department of Health, *Agency Analysis of HB 1441* (2024). On file with the Healthcare Regulation Subcommittee.
[9] S. 381.99, F.S.
[10] National Organization for Rare Disorders (NORD). *Project RDAC Year One* (2021). Available at https://rarediseases.org/wp-content/uploads/2021/11/NRD-2200-RDAC-Year1-Highlights_FNL.pdf (last visited January 20, 2024).
[11] National Organization for Rare Disorders (NORD). *About Us*. Available at https://rarediseases.org/about-us/ (last visited January 20, 2024).
[12] *Supra*, note 7.
[13] S. 381.99(4), F.S.; *See also*, the Rare Disease Advisory Council's 2nd Legislative Report at: https://www.floridahealth.gov/provider-and-partner-resources/rdac/_documents/RDACLegislativeReport2023Final_Draft.pdf

In addition to the diagnostic challenges presented by rare diseases, difficulties abound in the research of rare diseases. Due to the inherently small population affected by each rare disease, gathering sufficient sample sizes to conduct clinical trials is difficult. Patient data is scarce, and small sample sizes limit research possibilities. Patient registries are a means of overcoming some of the research limitations that exist due to the nature of rare diseases. Patient registries are organized systems that allow for the use of observational study methods to collect uniform data and evaluate specified outcomes for a population defined by a particular disease.[14]

Sickle cell disease (SCD) affects approximately 100,000 Americans, well within the definition of a rare disease, and is also the most prevalent inherited blood disorder in the US.[15] SCD affects mostly, but not exclusively, Americans of African ancestry. SCD is a group of inherited disorders in which abnormal hemoglobin cause red blood cells to buckle into the iconic 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.[16] 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.[17]

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 8 to 10 percent of African Americans carry sickle cell trait.[18]

While SCD is the most common inherited blood disorder in the US and is often diagnosed at birth through newborn screening programs,[19] patients with SCD experience many of the other trials associated with treating a rare disease. Until recently there was very little research development in the areas of managing, treating, or curing SCD, and a lack of understanding of SCD persists among many health care professionals.[20]

In 2023, the Legislature directed DOH to partner with a community-based sickle cell disease medical treatment and research center to establish and maintain a registry to track outcome measures of newborns who are identified as carrying a sickle cell hemoglobin variant.[21] DOH has since contracted with the Foundation for Sickle Cell Research for the implementation of the registry.[22] Under current law, only newborns who have been detected as carrying a sickle cell hemoglobin variant through the Newborn Screening Program are included in the registry. Parents may choose to have their child removed from the registry by submitting a form provided by DOH.[23] There is not a mechanism under current law for adults with SCD to be included in the registry.

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[14] Hageman, I.C., van Rooij, I.A., de Blaauw, I., et al. *A systematic overview of rare disease patient registries: challenges in design, quality management, and maintenance* (2023). Orphanet Journal of Rare Diseases 18, 106. https://doi.org/10.1186/s13023-023-02719-0

[15] National Heart, Lung, and Blood Institute, *What is Sickle Cell Disease?* Available at https://www.nhlbi.nih.gov/health/sickle-cell-disease (last visited June 26, 2023).

[16] Centers for Disease Control and Prevention, *What is Sickle Cell Disease?* Available at https://www.cdc.gov/ncbddd/sicklecell/facts.html (last visited January 24, 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 January 24, 2024).

[17] Centers for Disease Control and Prevention, *Complications of Sickle Cell Disease*. Available at https://www.cdc.gov/ncbddd/sicklecell/complications.html (last visited January 24, 2024).

[18] 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 January 20, 2024).

[19] 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 January 20, 2024).

[20] *See*, American Society of Hematology. *ASH Sickle Cell Disease Initiative*. Available at https://www.hematology.org/advocacy/sickle-cell-disease-initiative (last visited January 20, 2024).

[21] S. 383.147, F.S.

[22] Department of Health. *Contract Summary: Contract # CMO28*. On file with the Healthcare Regulation Subcommittee.

[23] S. 383.147, F.S.

Current law also directs the newborn's primary care physician to provide the parent or guardian of the newborn with information regarding the availability and benefits of genetic counseling.

Effect of Proposed Changes – Rare Diseases

Andrew John Anderson Pediatric Rare Disease Grant Program

HB 1441 establishes the Andrew John Anderson Pediatric Rare Disease Grant Program within DOH with the purpose of advancing the progress of research and cures for rare pediatric diseases through the award of grants through a competitive, peer-reviewed process. Grants are awarded by DOH, after consultation with the Rare Disease Advisory Council (RDAC).

Grants are awarded to universities or established research institutes in the state for scientific and clinical research to further the search for new diagnostics, treatments, and cures for rare pediatric diseases. The bill establishes a preference for grant proposals which foster collaboration among institutions, researchers, and community practitioners.

The bill directs DOH to appoint peer review panels of independent, scientifically qualified individuals to review the scientific merit of each proposal, and to share the results of such reviews with the RDAC which are to be considered in the recommendations for funding. The RDAC and peer review panels are to establish and follow rigorous guidelines for ethical conduct and adhere to a strict policy with regard to conflicts of interest.

Sickle Cell Disease Registry

HB 1441 creates a process through which parents may opt-out of their child's inclusion in the registry through a proactive process, rather than retroactively removing a child from the registry upon the parent's request. Parents may opt-out through a form obtained from DOH, or otherwise indicating their objection to DOH in writing.

The bill transfers the responsibility of informing parents of the availability and benefits of genetic counseling from the infant's primary care physician to DOH.

The bill also creates a mechanism for adults with SCD who are Florida residents to choose to be included in the registry. The bill directs DOH to prescribe by rule the process for an adult to opt into the registry.

Florida Newborn Screening Program

Current Situation

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.[24] 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.[25]

The NSP involves coordination across several entities, including the Bureau of Public Health Laboratories Newborn Screening Laboratory in Jacksonville (state laboratory), DOH Children's Medical Services (CMS) Newborn Screening Follow-up Program in Tallahassee, referral centers, birthing centers, and physicians throughout the state.[26] Health care providers in hospitals, birthing centers,

[24] S. 383.14(1), F.S.
[25] *Id*.
[26] S. 383.14, F.S.

perinatal centers, county health departments, and school health programs provide screening as part of the multilevel NSP screening process.[27] This includes a risk assessment for prenatal women, and risk factor analysis and screening for postnatal women and newborns as well as laboratory screening for select disorders in newborns.[28] 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.[29] The NSP is intended to screen all prenatal women and newborns, however, parents and guardians may choose to decline the screening.[30]

Health care providers perform non-laboratory NSP screening, such as hearing and risk factor analysis, and report the results to the Office of Vital Statistics. If necessary, health care providers refer patients to the appropriate health, education, and social services.[31] Health care providers in hospitals and birthing centers perform specimen collection for laboratory NSP screening by collecting a few drops of blood from the newborn's heel on a standardized specimen collection card. [32] The specimen card is then sent to the state laboratory for testing and the results are released to the newborn's health care provider. In the event that a newborn screen has an abnormal result, the newborn's health care practitioner,[33] 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.[34]

To administer the NSP, DOH is authorized to charge and collect a fee not to exceed $15 per live birth occurring in a hospital or birth center.[35] 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.[36] DOH bills hospitals and birth centers quarterly using vital statistics data to determine the amount to be billed.[37] DOH is authorized to bill third-party payers for the NSP tests and bills insurers directly for the cost of the screening.[38] DOH does not bill families that do not have insurance coverage.[39]

The Legislature established the Florida Genetics and Newborn Screening Advisory Council to advise DOH on disorders to be included in the NSP panel of screened disorders and the procedures for collecting and transmitting specimens.[40] Florida's NSP currently screens for 58 conditions, 55 of which are screened through the collection of blood spots. Screening of the other three conditions – hearing screening, critical congenital heart defect (CCHD) or pulse oximetry, and congenital cytomegalovirus (CCMV) targeted screening—are completed at the birthing facility through point-of-care testing.[41]

Newborn Hearing Screening

Section 383.145, F.S., requires a newborn hearing screening for all newborns in hospitals before discharge. The newborn hearing screening program (NBHS) is housed within DOH, which is

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[27] *Id.*
[28] *Id*.
[29] Florida Department of Health, *Florida Newborn Screening Guidelines*. Available at https://floridanewbornscreening.com/wp-content/uploads/NBS-Protocols-2022-FINAL.pdf (last visited December 27, 2023).
[30] S. 383.14(4), F.S.; Rule 64C-7.008, F.A.C.; The health care provider must attempt to get a written statement of objection to be placed in the medical record.
[31] *Id*.
[32] Florida Newborn Screening, *What is Newborn Screening?* Available at https://floridanewbornscreening.com/parents/what-is-newborn-screening/ (last visited December 27, 2023). *See also,* Florida Newborn Screening, *Specimen Collection Card*. Available at http://floridanewbornscreening.com/wp-content/uploads/Order-Form.png (last visited December 27, 2023).
[33] 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.
[34] *Id*.
[35] S. 383.145(3)(g)1., F.S.
[36] *Id.*
[37] S. 383.145(3)(g), F.S.
[38] S. 383.145(3)(h), F.S.
[39] *Supra*, note 26.
[40] S. 383.14(5), F.S.
[41] Department of Health, *Agency Analysis of HB 1441* (2024). On file with the Healthcare Regulation Subcommittee.

responsible for coordinating the statewide hearing screening and follow-up referral system. The NBHS program is funded through donations trust and federal grants from the Centers for Disease Control and Prevention and the Health Resources and Services Administration (HRSA).[42]

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.[43] 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 7 days after the birth or discharge from the facility.[44]

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.[45] When ordered by the treating physician, screening of a newborn's hearing must include auditory brainstem responses, or evoked otoacoustic emissions, or appropriate technology as approved by the United States Food and Drug Administration (FDA).[46]

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.[47] 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 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 United States, with approximately 2 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 HRSA federal grant requires collection of hearing screening data for infants and toddlers up to age 36 months.[48]

In 2020, 98% of newborns in Florida received a hearing screen. In 2020, 9,500 infants did not pass the hearing screening, and 261 infants were diagnosed with hearing loss. It is estimated that 71% (814) of infants born in birthing centers in 2020 did not receive a hearing screen.[49]

Effect of Proposed Changes – Florida Newborn Screening Program

HB 1441 expressly states that the health care practitioner present at birth, or responsible for primary care during the neonatal period, has the responsibility for administering the newborn screenings. The bill requires that health care practitioners responsible for administering newborn screenings shall prepare and send all specimen cards to the State Public Health Laboratory. The bill provides DOH rulemaking authority to implement these provisions.

The bill adds genetic counselors to the list of health care practitioners to whom the state laboratory may release NBS results.

The bill deletes several obsolete provisions related to the NBS program, including:

[42] *Id*.
[43] S. 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.
[44] S. 383.145(3)(d), F.S.
[45] S. 383.145(3)(f), F.S.
[46] S. 383.145(3)(i), F.S.
[47] *Supra*, note 42.
[48] *Id.*
[49] *Id.*

- The requirement that the NBS program and Healthy Start to coordinate with the Florida Department of Education;
- Statutory references to a specific disease, phenylketonuria, which is included in the NBS program regimen;
- The requirement for DOH's Office of Inspector General to certify the financial operations of the NBS program;[50]
- The requirement for DOH to furnish physicians, county health departments, perinatal centers, birth centers, and hospitals with forms related in NBS.

Environmental Risk Screening

The bill removes current language relating to environmental risk screening from the NBS program and creates a separate section of law wherein the requirements for environmental risk screening are outlined. The requirements for environmental risk screening under the bill are consistent with current law.

Newborn Hearing Screening

The bill requires licensed birth centers to conduct newborn screenings before the newborn is discharged, rather than requiring the newborn be referred for testing outside of the birth center. The bill also requires that all newborns who do not pass the hearing screening are, within seven days of birth, referred for congenital cytomegalovirus testing to occur before the infant is 21 days of age.

The bill defines "toddler," as a child from 12 months to 36 months of age. Under current law, a physician-ordered hearing screening of a newborn must include auditory brainstem responses, or evoked otoacoustic emissions, or appropriate technology as approved by the US Food and Drug Administration. The bill expands these requirements to apply to physician-ordered screenings for infants and toddlers. The results of such tests must be reported to DOH within seven days of the receipt of test results.

B. SECTION DIRECTORY:

Section 1: Amends s. 381.0101, F.S., relating to environmental health professionals.
Section 2: Creates s. 381.991, F.S., relating to the Andrew John Anderson Pediatric Rare Disease Grant Program.
Section 3: Amends s. 383.14, F.S., relating to screening for metabolic disorders, other hereditary and congenital disorders, and environmental risk factors.
Section 4: Amends s. 383.145, F.S., relating to newborn and infant hearing screening.
Section 5: Amends s. 383.147, F.S., relating to newborn and infant screenings for sickle cell hemoglobin variants; registry.
Section 6: Creates s. 383.148, F.S., relating to environmental risk screening.
Section 7: Amends s. 383.318, F.S., relating to postpartum care for birth center clients and infants.
Section 8: Amends s. 395.1053, F.S., relating to postpartum education.
Section 9: Amends s. 456.0496, F.S., relating to provision of information on eye and vision disorders to parents during planned out-of-hospital births.
Section 10: Provides an effective date of July 1, 2024.

[50] *Id*. DOH reports that the current process is duplicative as NBS program funds are placed in a state trust fund subject to the rules governing state trust funds.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None.

2. Expenditures:

The provision of Section 2 (the Andrew John Anderson Pediatric Rare Disease Grant Program) of the bill is subject to appropriation.

See *Fiscal Comments*.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Private research institutions who are eligible for the Andrew John Anderson Pediatric Rare Disease Grant Program may experience a positive fiscal impact from access to this additional funding.

D. FISCAL COMMENTS:

Andrew John Anderson Pediatric Rare Disease Grant Program

According to DOH, the $500,000 that was allocated in the 2023 General Appropriations Act to fund research grants for pediatric rare diseases is intended fund the inaugural year of the Andrew John Anderson Pediatric Rare Disease Grant Program.[51]

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

Not applicable. The bill does not appear to affect county or municipal governments.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

The bill provides sufficient rulemaking authority to implement the provisions of the bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

[51] *Id*.

IV. AMENDMENTS/COMMITTEE SUBSTITUTE CHANGES

On January 29, 2024, the Health Care Appropriations Subcommittee adopted an amendment and reported the bill favorably as a committee substitute. The amendment removed language related to the Telehealth Minority Maternity Care Pilot Program.