HOUSE OF REPRESENTATIVES STAFF FINAL BILL ANALYSIS

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

FINAL HOUSE FLOOR ACTION: 114 **Y's** 0 **N's** **GOVERNOR'S ACTION:** N/A

SUMMARY ANALYSIS

CS/CS/HB 1441 passed the House on March 6, 2024, as CS/CS/CS/SB 1582 as amended. The Senate concurred with the House amendment to the Senate bill, and subsequently passed the bill as amended on March 7, 2024.

The bill makes changes to several programs administered under the Department of Health (DOH).

DOH certifies Environmental health professionals (EHPs) to perform evaluations of environmental or sanitary conditions in specific environmental health program areas. 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 in 2021 to assist DOH in providing recommendations to improve health outcomes for individuals with rare diseases residing in the state. 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 pediatric rare diseases.

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 with sickle cell disease or sickle cell trait. The bill authorizes adults to opt into the registry, and revises 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, as well as environmental risk factors. The bill revises the NSP to specify the responsibilities of relevant health care practitioners and repeal obsolete provisions. The bill standardizes hearing screening practices for newborns and requires screening results for children up to 36 months of age be reported to DOH.

The Florida Cancer Control and Advisory Council (Council) monitors Florida's cancer burden and recommends changes in policies, systems, and environments that lead to cancer-related health outcomes. The bill adds an additional member to the Council representing Mayo Clinic in Jacksonville.

The bill requires DOH to open an additional 90-day window for *Pigford/In Re Black Farmers* litigants to cure deficiencies in their applications for Medical Marijuana Treatment Center licensure. The bill revises licensure requirements for this applicant group, and requires DOH to grant licenses to all qualified applicants.

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.

Subject to the Governor's veto powers, the effective date of this bill is July 1, 2024; except for the provision related to MMTC license applications which is effective upon the act becoming law.

I. SUBSTANTIVE INFORMATION

A. EFFECT OF 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]

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.[2] 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.[3]

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.[4]

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.[5]

Effect of the Bill – 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 EHP 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] S. 381.0101(4)(e), F.S.
[3] *Supra*, note 5.
[4] Ch. 2020-150, L.O.F.
[5] 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.

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

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[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 March 18, 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 March 18, 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 March 18, 2024).
[11] National Organization for Rare Disorders (NORD). *About Us*. Available at https://rarediseases.org/about-us/ (last visited March 18, 2024).
[12] *Supra*, note 7.
[13] S. 381.99(4), F.S.; *See also*, the Rare Disease Advisory Council, *2nd Legislative Report* (2023). Available at https://www.floridahealth.gov/provider-and-partner-resources/rdac/_documents/RDACLegislativeReport2023Final_Draft.pdf (last visited March 18, 2024).

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 no 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 March 15, 2024).

[16] Centers for Disease Control and Prevention, *What is Sickle Cell Disease?* Available at https://www.cdc.gov/ncbddd/sicklecell/facts.html (last visited March 18, 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 March 14, 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 March 18, 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 March 18, 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# (last visited March 14, 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 March 18, 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 the Bill – Rare Diseases

Andrew John Anderson Pediatric Rare Disease Grant Program

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

DOH will award grants 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 pediatric rare 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

The bill 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.

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]

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

The NSP utilizes a multilevel screening process including a prenatal risk assessment for pregnant women, and risk factor analysis and screening for postnatal women and newborns, as well as laboratory screening for select disorders in newborns.[26] 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.[27] The NSP is intended to screen all prenatal women and newborns, however, parents and guardians may choose to decline the screening.[28]

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, and referral centers, birthing centers, and physicians throughout the state.[29] Health care providers in hospitals, birthing centers, perinatal centers, county health departments, and school health programs provide screening as part of the multilevel NSP screening process.[30]

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.[31] 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] DOH bills hospitals and birth centers quarterly using vital statistics data to determine the amount to be billed.[33] DOH is authorized to bill third-party payers for the NSP tests and bills insurers directly for the cost of the screening.[34] DOH does not bill families that do not have insurance coverage.[35]

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.[36] Florida's NSP currently screens for 58 conditions, 55 of which are screened through the collection of blood spots.[37] Health care providers in hospitals and birthing centers 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.[38] Health care providers also perform non-laboratory NSP screening, such as hearing screening, pulse oximetry tests for critical congenital heart defect, 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.[39] 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.[40]

Newborn Hearing Screening

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[26] *Id*.
[27] Florida Department of Health, *Florida Newborn Screening 2022 Guidelines*. Available at https://floridanewbornscreening.com/wp-content/uploads/NBS-Protocols-2022-FINAL.pdf (last visited March 11, 2024).
[28] 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.
[29] S. 383.14, F.S.
[30] *Id.*
[31] S. 383.145(3)(g)1., F.S.
[32] *Id.*
[33] S. 383.145(3)(g), F.S.
[34] S. 383.145(3)(h), F.S.
[35] S. 383.14, F.S.
[36] S. 383.14(5), F.S.
[37] Department of Health, *Agency Analysis of HB 1441* (2024). On file with the Healthcare Regulation Subcommittee.
[38] Florida Newborn Screening Program, *What is Newborn Screening?* Available at https://floridanewbornscreening.com/parents/what-is-newborn-screening/ (last visited March 11, 2024). *See also,* Florida Newborn Screening, *Specimen Collection Card*, http://floridanewbornscreening.com/wp-content/uploads/Order-Form.png (last visited March 11, 2024).
[39] *Id*.
[40] *Supra*, note 37.

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 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).[41]

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.[42] 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.[43]

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.[44] 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).[45]

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.[46] 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.[47]

In 2020, 98 percent of newborns in Florida received a hearing screening. In 2020, 9,500 infants did not pass the hearing screening, and 261 infants were diagnosed with hearing loss. It is estimated that 71 percent (814) of infants born in birthing centers in 2020 did not receive a hearing screening.[48]

Effect of the Bill – Newborn Screening Program

The bill expressly makes the health care practitioner present at birth, or responsible for primary care during the neonatal period, responsible for administering newborn screenings. The bill requires these health care practitioners to prepare and send all specimen cards to the state laboratory. The bill provides DOH rulemaking authority to implement these provisions.

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[41] *Id*.
[42] 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.
[43] S. 383.145(3)(d), F.S.
[44] S. 383.145(3)(f), F.S.
[45] S. 383.145(3)(i), F.S.
[46] *Supra*, note 37.
[47] *Id.*
[48] *Id.*

The bill deletes obsolete provisions related to the NBS program. The bill deletes references to a specific disease, phenylketonuria, which are remnants of the original NBS program which was much narrower in scope at its inception. The NBS program has since developed into a comprehensive screening program wherein screened disorders, which include phenylketonuria, are based on recommendations from the Florida Genetics and Newborn Screening Advisory Council, as well as the federal Advisory Committee on Heritable Disorders in Newborns and Children. The bill also deletes the requirement for DOH to furnish physicians, county health departments, perinatal centers, birth centers, and hospitals with forms related in NBS, which has been made obsolete due to the use of electronic processes for the transmission of such forms.

The bill also removes a requirement that DOH must consult with the Department of Education (DOE) in the development of rules relating to the NBS program which are not directly related to DOE's purview; such as screening requirements and the state laboratory's testing procedures. Similarly, the bill also removes the requirement for the DOH Office of Inspector General to certify the financial operations of the NBS program, which DOH considers duplicative as NBS program funds are placed in a state trust fund subject to the rules governing state trust funds.

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

Environmental Risk Screening

Under current law, the provisions relating to environmental risk screening are intertwined with the metabolic disorder screening processes and requirements. The bill extricates the environmental risk screening provisions from the screening for metabolic disorders and creates a standalone section of law outlining the environmental risk screening requirements, similar to the statutory structure of the newborn hearing screening component of the NBS program.

The requirements for environmental risk screening under the bill are largely consistent with current law, but for the express requirement that a prenatal risk screening be conducted at a pregnant woman's first prenatal appointment, and the postnatal risk screening be conducted after the birth of an infant and prior to discharge from the hospital.

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 U.S. Food and Drug Administration. The bill expands these requirements to apply to physician-ordered screenings for infants and toddlers, which the results of such tests must be reported to DOH within seven days of the receipt of test results.

Florida Cancer Control and Research Advisory Council

Current Situation

The Florida Cancer Control and Advisory Council (council) is an advisory body appointed to function on a continuing basis for the study of cancer and to make recommendations on solutions and policy

alternatives to the Board of Governors and the State Surgeon General.[49] The council closely monitors Florida's cancer burden and recommends changes in policies, systems, and environments that lead to improved prevention, early detection, high-quality treatment, and increased cancer survival rates.[50]

The council consists of 15 members:[51]

- The State Surgeon General or his or her designee within the DOH;
- A representative of the H. Lee Moffitt Cancer Center and Research Institute, Inc.;
- A representative of the Sylvester Comprehensive Cancer Center of the University of Miami;
- A representative of the University of Florida Shands Cancer Center;
- A representative of the American Cancer Society;
- A representative of the Association of Community Cancer Centers;
- A member of the Florida Hospital Association who specializes in the field of oncology;
- A member of the Florida Medical Association who specializes in the field of oncology;
- A representative of the Florida Nurses Association who specializes in the field of oncology;
- A representative of the Florida Osteopathic Medical Association who specializes in the field of oncology;
- A specialist in pediatric oncology research or clinical care appointed by the Governor;
- A specialist in oncology clinical care or research appointed by the President of the Senate;
- A current or former cancer patient or a current or former caregiver to a cancer patient appointed by the Speaker of the House of Representatives;
- A member of the House of Representatives appointed by the Speaker of the House of Representatives; and
- A member of the Senate appointed by the President of the Senate.

Council members serve four-year terms. Eight members constitute a quorum for the purpose of exercising all of the powers of the council.[52]

Effect of the Bill - Florida Cancer Control and Research Advisory Council

The bill increases the membership of the council from 15 to 16 people, and requires the additional member to be a representative of the Mayo Clinic in Jacksonville. The bill also adjusts the quorum so that nine members, instead of eight, constitute a quorum for the purpose of exercising the powers of the council.

Medical Marijuana Treatment Centers

Current Situation

DOH licenses medical marijuana treatment centers (MMTCs) to ensure reasonable statewide access to medical use marijuana for registered patients.[53]

The regulatory structure for the medical use of marijuana and the licensing of MMTCs was first established by the Legislature in 2017. Initially, DOH was required to grant MMTC licenses to dispensing organizations previously licensed under the Compassionate Medical Cannabis Act

[49] S. 1004.435, F.S.
[50] Florida Cancer Control and Research Advisory Council. *The State of Cancer in Florida: CCRAB Annual Report 2024*. Available at https://www.ccrab.org/?a=Files.Serve&File_id=C388CD5A-94E1-4342-B946-D21F872724CC (last visited March 18, 2024).
[51] S. 1004.435(4), F.S.
[52] S. 1004.435(4), F.S.
[53] S. 381.986(8), F.S.

(CMCA)[54] by July 3, 2017,[55] as well as ten additional MMTC licenses based upon a competitive application process with a preference for certain categories of applicants.[56] One of the ten additional MMTC licenses was to be awarded to an applicant that is a recognized class member of *Pigford v. Glickman*, 185 F.R.D. 82 (D.D.C. 1999), or *In Re Black Farmers Litig.*, 856 F. Supp. 2d 1 (D.D.C. 2011), using a competitive application process.[57]

In October 2021, DOH adopted a rule establishing the requirements for the competitive application process for the one *Pigford/In Re Black Farmers* MMTC license.[58] In December 2021, DOH adopted a rule establishing March 21-25, 2022, as the application window for this license.[59] There were 12 applicants for this one MMTC license.[60]

In 2023, the Legislature required DOH to issue medical marijuana licenses to applicants for the *Pigford/In Re Black Farmers* litigants medical marijuana license for all applicants that:

- Received a notice from DOH of its intent to deny or approve the application and the application had no deficiencies; or
- Received a final determination from DOH in an administrative challenge that applicant met all requirements for licensure, even if the applicant died during the challenge process; or
- Had deficiencies in its application but cures such deficiencies within 90 days.

While applicants were given a 90-day window to cure any deficiencies in their applications, they were still obligated to meet the existing requirements for MMTC licensure in order to be issued a license. One such requirement is that the applicant must have been registered to do business in Florida for the preceding five years.[61]

Effect of the Bill - Medical Marijuana Treatment Centers

The bill requires DOH to open an additional 90-day window wherein the existing applicants for the *Pigford/In Re Black Farmers* MMTC license may cure any deficiencies with their application. The bill requires DOH issue a license to applicants who are able to cure the deficiencies within the 90-day period.

Under the bill, DOH must consider the application cured of all deficiencies, and thus issue a license to the applicant, if the sole remaining deficiency is either:

- A failure to meet the requirement that the applicant must have been registered to do business in Florida for the preceding five years, thus effectively nullifying this requirement for this group of applicants; or
- The applicant died after March 25, 2022, in which case DOH must issue the license to the heirs of the applicant.

[54] The CMCA was enacted in 2014, prior to enactment of Art. X, Sec. 29 of the Florida Constitution which established Florida's current medical marijuana program.
[55] S. 381.986(8)(a)1, F.S.
[56] S. 381.986(8)(a)2, F.S.
[57] S. 381.986(8)(a)2.b, F.S. These cases were class action discrimination suits between the U.S. Department of Agriculture (USDA) and black farmers. The suits alleged that USDA had discriminated against black farmers on the basis of race and failed to investigate or properly respond to complaints from 1983 to 1997. Settlement was reached in *Pigford v. Glickman* in 1999, for $1.06 billion and was reached in *In re Black Farmers Discrimination Litigation* in 2010, for $1.25 billion. *The Pigford Cases: USDA Settlement of Discrimination Suits by Black Farmers*. Available at https://www.everycrsreport.com/reports/RS20430.html (last visited March 15, 2024).
[58] Rule 64ER21-16, F.A.C.
[59] Rule 64ER21-19, F.A.C.
[60] *2022 Pigford/Black Farmers Litigation MMTC Application Process*, Florida Department of Health, Office of Medical Marijuana Use, available at https://knowthefactsmmj.com/mmtc/2022-pigford-bfl-mmtc-application-process/ (last visited March 14, 2024).
[61] S. 381.986(8)(b), F.S.

Subject to the Governor's veto powers, the effective date of this bill is July 1, 2024; except for the provision related to MMTC license applications which is effective upon the act becoming law.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None.

2. Expenditures:

The Andrew John Anderson Pediatric Rare Disease Grant Program established in the bill is subject to appropriation. The Fiscal Year 2024-2025 General Appropriations Act appropriated $500,000 in recurring funds from the General Revenue Fund to DOH for a pediatric rare disease research grant program.[62]

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.

Any of the remaining *Pigford v. Glickman/In Re Black Farmers* MMTC license applicants who have previously been unsuccessful in obtaining an MMTC license who are able to obtain a license under the bill's provision will realize the economic benefits of obtaining a MMTC license.

D. FISCAL COMMENTS:

None.

[62] Fiscal Year 2024-2025, General Appropriations Act, Conference Report for House Bill 5001, line 546a.