HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: CS/HB 349 Sickle Cell Care Management and Treatment Education for Physicians
SPONSOR(S): Healthcare Regulation Subcommittee, Robinson, F.
TIED BILLS: **IDEN./SIM. BILLS:** SB 552

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Healthcare Regulation Subcommittee	15 Y, 0 N, As CS	Osborne	McElroy
2) Health Care Appropriations Subcommittee			
3) Health & Human Services Committee			

SUMMARY ANALYSIS

Sickle cell disease (SCD) is the most common inherited blood disorder in the United States, affecting approximately 100,000 Americans. 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. 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.

Treatment for SCD has improved significantly in recent decades. Appropriate pharmaceutical treatments and evidence-based management protocols have the capacity to significantly improve the quality of life for people with SCD. In spite of the improvements in treatments for SCD, there significant underutilization among patients, due in part to gaps in understanding of the disease and its treatments among health care practitioners.

CS/HB 349 requires specified health care practitioners to complete two hours of continuing education on the subject of sickle care disease management as a part of every second biennial licensure or certification renewal. The bill specifies that the course shall consist of education specific to SCD, including evidence-based treatment protocols for patients of all ages, continuing patient and family education, periodic comprehensive health evaluations and other disease-specific health maintenance services, psychosocial care, genetic counseling, and pain management.

The Board of Medicine, the Board of Osteopathic Medicine, and the Board of Nursing are responsible for implementing the provisions of the bill and approving appropriate continuing education courses. The bill authorizes each board to adopt rules to implement the provisions of the bill.

The continuing education course required under the bill may count toward a licensee's total number of continuing education requirements for professionals required to complete 30 or more hours of continuing education biennially. The bill allows a professional holding two or more licenses subject to the requirements of the bill to satisfy such requirement through the completion of one board-approved course. Failure to comply with the requirements of the bill constitute grounds for disciplinary action.

The bill has an insignificant, negative fiscal impact on DOH, and no fiscal impact on local government.

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

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Background

Sickle Cell Disease

Sickle cell disease (SCD) is the most common inherited blood disorder in the United States, affecting approximately 100,000 Americans.[1] SCD affects mostly, but not exclusively, Americans of African ancestry.[2] 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.[3]

The severity of complications from SCD generally worsen as people age, but treatment and prevention strategies can mitigate complications and lengthen the lives of people with SCD.[4] SCD was historically perceived as a childhood disease due to high rates of childhood mortality, however, more than 90 percent of those living with the disease today are expected to survive into adulthood.[5] Roughly 60 percent of individuals with SCD in the US today are adults, but the life expectancy of individuals with SCD remains approximately 22 years shorter than the general population.[6]

Management of SCD

SCD management primarily focuses on treating and preventing complications caused by the disease such as acute pain episodes, infection, stroke, vision loss, and severe anemia. The most well-researched treatments for SCD relate to mitigating the risk of infection and stroke in children. There is a lack of research-driven data specific to adult populations with SCD.[7]

Stroke is one of the most common and devastating complications of SCD.[8] Blood transfusions may be used to treat acute episodes of elevated stroke risk, or through chronic transfusion therapy which reduces a person's overall stroke risk as well as preventing painful vaso-occlusive events.[9] Chronic

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[1] National Heart, Lung, and Blood Institute, *What is Sickle Cell Disease?* Available at https://www.nhlbi.nih.gov/health/sickle-cell-disease (last visited January 30, 2024).
[2] Centers for Disease Control and Prevention, *Data & Statistics on Sickle Cell Disease*. Available at https://www.cdc.gov/ncbddd/sicklecell/data.html (last visited January 30, 2024).
[3] 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).
[4] 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).
[5] DiMartino, L. D., Baumann, A. A., Hsu, L. L., Kanter, J., Gordeuk, V. R., Glassberg, J., Treadwell, M. J., Melvin, C. L., Telfair, J., Klesges, L. M., King, A., Wun, T., Shah, N., Gibson, R. W., Hankins, J. S., & Sickle Cell Disease Implementation Consortium (2018). *The sickle cell disease implementation consortium: Translating evidence-based guidelines into practice for sickle cell disease.* American journal of hematology, 93(12), E391–E395. https://doi.org/10.1002/ajh.25282.
[6] Lubeck D, Agodoa I, Bhakta N, et al. (2019) *Estimated Life Expectancy and Income of Patients With Sickle Cell Disease Compared With Those Without Sickle Cell Disease*. JAMA Netw Open. 2019;2(11):e1915374. doi:10.1001/jamanetworkopen.2019.15374. Available at https://jamanetwork.com/journals/jamanetworkopen/article-abstract/2755485 (last visited January 30, 2024).
[7] Adams-Graves, P. & Bronte-James, L. *Recent Treatment Guidelines for Managing Adult Patients with Sickle Cell Disease: Challenges in Access to Care, Social Issues, and Adherence*. (2016). Expert Review of Hematology, 9:6, 511-614. http://dx.doi.org/10.1080/17474086.2016.1180242
[8] U.S. Department of Health and Human Services, National Heart, Lung, and Blood Institute. *Evidence-Based Management of Sickle Cell Disease: Expert Panel Report* (2014). Available at https://www.nhlbi.nih.gov/health-topics/evidence-based-management-sickle-cell-disease (last visited January 31, 2024).
[9] Brandow, A.M., Panepinto, J.A. (2010). *Hydroxyurea Use in Sickle Cell Disease: The Battle with Low Prescription Rates, Poor Patient Compliance, and Fears of Toxicities*. Expert Reviews: Hematology. DOI: 10.1586/EHM.10.22

transfusion therapy has been shown to improve health-related quality of life in children with SCD.[10] There are, however, risks associated with frequent blood transfusions and chronic transfusion therapy can be logistically and financially difficult for caregivers to manage.[11] A transcranial Doppler ultrasound (TCD), is a specialized ultrasound device capable of detecting elevated stroke risk.[12] For children ages 2-16 with SCD who have a heightened risk of stroke, annual TCD screening is recommended by the American Society of Hematology to monitor stroke risk and prevent stroke.[13]

People with SCD are generally at a higher risk of severe bacterial infections due to poor spleen function, but fatality is especially high among young children and infants who lack the immune response necessary to combat infection. Defective or reduced spleen function begins early in the first year of life for infants with SCD.[14] To protect against life-threatening pneumococcal bacterial infection, daily oral penicillin is the standard of care for children from infancy through age five.[15]

In addition to daily oral penicillin and routine screening to monitor stroke risk in children, there are other pharmaceutical treatments available to manage the symptoms of SCD, reduce the long-term health impacts of the disease, and improve quality of life for children and adults with SCD. Hydroxyurea is an oral medication taken once daily which has been proven to be effective at reducing a person's pain episodes, mitigating stroke risk, and preventing organ damage.[16] Hydroxyurea is generally safe for both children and adults and is recommended for patients with certain forms of SCD experiencing "frequent pain episodes" or acute chest syndrome.[17]

Opioids are commonly used to treat the severe acute pain that results from vaso-occlusive episodes. Opioids are not recommended for treatment of the chronic pain that is associated with SCD due to the significant risks of overdose and addiction associated with frequent opioid use. Opioids are, however, very effective for managing acute severe pain in acute settings and as such the National Heart Lung and Blood Institute recommends rapid initiation of opioids for patients visiting the emergency department for a vaso-occlusive pain episode.[18]

More recent pharmaceutical developments for the treatment of SCD include L-glutamine, Voxelotor, and Crizanlizumab. L-glutamine in an essential amino acid which was approved by the FDA in 2017 for the treatment of SCD in adults and children over five years of age. The mechanism of action of L-glutamine is not well understood, however, it has been shown to reduce a patient's number of sickle cell crisis episodes.[19] Voxelotor and Crizanlizumab are two disease modifying drugs approved by the FDA in 2019. The drugs may be beneficial for different subgroups of SCD patients for whom other treatments have proven insufficient or ineffective. Voxelotor and Crizanlizumab act through different

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[10] Beverung, L.M., Strouse, J.J., Hulbert, M.L. (2015) *Health-related Quality of Life in Children with Sickle Cell Anemia: Impact of Blood Transfusion Therapy*. American Journal of Hematology. http://doi.org/10/1002/ajh.2387

[11] *Supra*, note 12.

[12] Runge, A., Brazel, D., Pakbaz, Z. (2022). *Stroke in Sickle Cell Disease and the Promise of Recent Disease Modifying Agents*. Journal of the Neurological Sciences. http://doi.org/10.1016/j.jns.2022.120412

[13] DeBaun, M., et al. *American Society of Hematology 2020 guidelines for sickle cell disease: prevention, diagnosis, and treatment of cerebrovascular disease in children and adults*. (2020). Blood Advances; 4 (8): 1554–1588. doi: https://doi.org/10.1182/bloodadvances.2019001142

[14] U.S. Department of Health and Human Services, National Heart, Lung, and Blood Institute. *Evidence-Based Management of Sickle Cell Disease: Expert Panel Report* (2014). Available at https://www.nhlbi.nih.gov/health-topics/evidence-based-management-sickle-cell-disease (last visited January 31, 2024).

[15] 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). Amoxicillin may also be prescribed for this purpose. In patients with a known or suspected penicillin allergy, erythromycin is prescribed.

[16] *Id.*

[17] U.S. Department of Health and Human Services, National Heart, Lung, and Blood Institute. *Evidence-Based Management of Sickle Cell Disease: Expert Panel Report* (2014). Available at https://www.nhlbi.nih.gov/health-topics/evidence-based-management-sickle-cell-disease (last visited January 31, 2024).

[18] *Id. See also*, Smeltzer, M.P., Howell, K.E., Treadwell, M. (2021). *Identifying barriers to evidence-based care for sickle cell disease: results from the Sickle Cell Disease Implementation Consortium cross-sectional survey of healthcare providers in the USA*. BMJ Open 2021. DOI: 10.1136/bmjopen-2021-050880

[19] Quinn C. T. (2018). *l-Glutamine for sickle cell anemia: more questions than answers*. Blood, 132(7), 689–693. https://doi.org/10.1182/blood-2018-03-834440. *See also*, Ballas S. K. (2020). *The Evolving Pharmacotherapeutic Landscape for the Treatment of Sickle Cell Disease*. Mediterranean journal of hematology and infectious diseases, 12(1), e2020010. https://doi.org/10.4084/MJHID.2020.010

mechanisms, but both mitigate the harmful effects of damaged red blood cells in the body. There is ongoing research into their impact on other SCD morbidities.[20]

Curative Treatments for SCD

On December 8, 2023, the FDA approved the first two gene therapies for the treatment of SCD. The products, Casgevy and Lyfgenia, are cell-based gene therapies approved for the treatment of SCD in patients 12 years of age or older. Both products are made from the patients' own blood stem cells, which are modified, and administered to the patient as a one-time, single-dose infusion as part of a hematopoietic (blood) stem cell transplant. Prior to treatment, a patients' stem cells are collected, and then the patient must undergo high-dose chemotherapy, a process that removes cells from the bone marrow so they can be replaced with the modified cells.[21]

The FDA-approved gene therapies have not reached full market availability, but the costs are anticipated to be as high as $2 to million per patient.[22] It is yet to be determined how insurance companies or Medicaid will cover the treatment.[23]

Prior to the approval of these gene therapy treatments, the only treatment for SCD with curative potential was a matched/related hematopoietic stem cell transplant (HSCT). HSCT has been shown to be highly effective as a cure, though outcomes are more favorable when the transplant is performed before age 16 and with a matched sibling donor.[24] While highly curative, HSCT poses significant risks including transplant rejection that can result in the patient's death.[25] The procedure is infrequently performed due to the high cost,[26] the limited number of capable transplant centers, the strenuous preparation regimen and significant risks,[27] and the need for a genetically matched donor.[28]

Barriers to Care for SCD

While SCD is the most common inherited blood disorder in the US and is often diagnosed at birth through newborn screening programs,[29] patients with SCD often experience significant barriers to accessing appropriate care. Barriers to care include lack of insurance, unmet transportation needs, and provider inexperience and lack of knowledge about SCD. There is a limited number of knowledgeable health care professionals with expertise in the management of SCD, and mistrust among patients and bias among providers continue to affect access to and quality of care.[30]

Recent decades have brought major scientific advancements in understanding the biological mechanisms of SCD, the development of new pharmaceutical treatments, the establishment of evidence-based treatment protocols, and methods for mitigating the risk of catastrophic

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[20] *Supra*, note 12.
[21] US Food & Drug Administration, *FDA Approves First Gene Therapies to Treat Patients with Sickle Cell Disease* (2023). Available at https://www.fda.gov/news-events/press-announcements/fda-approves-first-gene-therapies-treat-patients-sickle-cell-disease (last visited January 30, 2024).
[22] National Heart, Lung, and Blood Institute. *FDA approval of gene therapies for sickle cell disease: Q&A with NHLBI Director Dr. Gary Gibbons and NHLBI's Division of Blood Diseases and Resources Director Dr. Julie Panepinto* (2023). Available at https://www.nhlbi.nih.gov/news/2023/fda-approval-gene-therapies-sickle-cell-disease-dr-gibbons-dr-panepinto (last visited January 30, 2024).
[23] MacMillan, C., *Casgevy and Lyfgenia: Two Gene Therapies Approved for Sickle Cell Disease*. (2023). Yale Medicine. Available at https://www.yalemedicine.org/news/gene-therapies-sickle-cell-disease (last visited January 30, 2023).
[24] Gluckman, E., Cappelli, B., Bernaudin, F., et al. (2017). *Sickle cell disease: an international survey of results of HLA-identical sibling hematopoietic stem cell transplantation*. Blood, 129(11), 1548–1556. https://doi.org/10.1182/blood-2016-10-745711
[25] Ashorobi D, Bhatt R. *Bone Marrow Transplantation in Sickle Cell Disease*. (2022). In: StatPearls. Treasure Island (FL): StatPearls Publishing. Available at https://www.ncbi.nlm.nih.gov/books/NBK538515/ (last visited January 31, 2024).
[26] *Supra*, note 17. HSCT is estimated to cost approximately $1 million to $2 million per person.
[27] *Supra*, note 17.
[28] Salcedo, J., Bulovic, J., & Young, C. (2021). *Cost-effectiveness of a Hypothetical Cell or Gene Therapy Cure for Sickle Cell Disease.* Scientific Reports. https://doi.org/10.1038/s41598-021-90405-1
[29] 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).
[30] Sickle Cell Disease Coalition, *State of Sickle Cell Disease: 2020 Report Card* (2020). Available at http://www.scdcoalition.org/pdfs/SCD%20Report%20Card%202020.pdf (last visited January 31, 2024).

complications.[31] Collectively, these advancements provide the means for significantly improving the quality of life for many patients with SCD; however, few of these interventions are utilized to their full potential.

The nature of SCD inherently leads to a greater use of health care services compared to the general population, but gaps in access to appropriate care are common and lead to unmitigated health crises and a greater consumption of costly emergency medical services.[32] Health care practitioners who have not specialized in the treatment of SCD express discomfort in prescribing essential treatments for SCD,[33] and a lack of knowledge regarding recent treatment developments.[34]

Access to adequate care is especially challenging for young adults transitioning from pediatric to adult care settings.[35] While SCD has historically been associated with childhood mortality, more than 90 percent of those living with the disease are expected to survive into adulthood today.[36] The system of care for SCD has developed with a focus on pediatric patients; as a result, patients with SCD are more likely to receive well-managed preventative care as children through specialized pediatric programs. Patients aging out of pediatric care and transitioning into adult care are less likely to have access to consistent and appropriate SCD care, which leads to higher rates of emergency department reliance than other age groups.[37]

SCD care in emergency settings presents additional challenges. Patients with SCD who present to emergency care settings in the midst of pain crises may be perceived as drug seekers or abusers and have their pain severity doubted and undertreated.[38] Educational gaps and biases among providers, staff, and patients create barriers to communication and trust, and erode the provider–patient relationship, which can result in inadequate or inappropriate treatment of patients.[39]

Florida's Medicaid SCD Population

In 2022, the Legislature directed the Agency for Health Care Administration (AHCA) to conduct a study assessing Florida's population of Medicaid enrollees with SCD and their utilization of specific health care services.[40] The Florida Medicaid Study of Enrollees with Sickle Cell Disease (the study) analyzed data from 2018 through 2021 and found that Florida's rate of Medicaid enrollees with SCD was twice

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[31] American Society of Hematology. *ASH Sickle Cell Disease Initiative: Sickle Cell Disease Timeline*. Available at https://www.hematology.org/advocacy/sickle-cell-disease-initiative/scd-timeline (last visited January 30, 2024).
[32] DiMartino, L. D., Baumann, A. A., Hsu, L. L., Kanter, J., Gordeuk, V. R., Glassberg, J., Treadwell, M. J., Melvin, C. L., Telfair, J., Klesges, L. M., King, A., Wun, T., Shah, N., Gibson, R. W., Hankins, J. S., & Sickle Cell Disease Implementation Consortium (2018). *The sickle cell disease implementation consortium: Translating evidence-based guidelines into practice for sickle cell disease.* American journal of hematology, 93(12), E391–E395. https://doi.org/10.1002/ajh.25282. *See also*, Brousseau, D.C., Owens, P.L., Mosso, A.L., Panepinto, J.A., Steiner, C.A. (2010). *Acute Care Utilization and Rehospitalizations for Sickle Cell Disease*. JAMA. 2010;303(13):1288–1294. doi:10.1001/jama.2010.378
[33] Lanzkron S, Haywood C Jr, Hassell KL, Rand C. *Provider barriers to hydroxyurea use in adults with sickle cell disease: a survey of the sickle cell disease adult provider network*. (2008) Journal of the National Medical Association. 100(8): 968-973. https://doi.org/10.1016/S0027-9684(15)31419-X
[34] Robinson, K., Esgro, R., Cooper, S., LoPresti, M., & Carson, B. *Identifying and Addressing Knowledge and Confidence Gaps Regarding the Management of Patients with Sickle Cell Disease Via Engaging Continuing Medical Education*. (2023). Blood 142 (Supplement 1): 7228. doi: https://doi.org/10.1182/blood-2023-177576
[35] Hemker, B., Brouseau, D., Yan, K., Hoffmann, R., & Panepinto. *When Children with Sickle Cell Disease Become Adults: Lack of Outpatient Care Leads to Increased Use of the Emergency Department* (2011). American Journal of Hematology. 86:10, 863-865. https://doi.org/10.1002/ajh.22106
[36] *Id*.
[37] Blinder, M. A., Duh, M. S., Sasane, M., Trahey, A., Paley, C., & Vekeman, F. (2015). *Age-Related Emergency Department Reliance in Patients with Sickle Cell Disease*. The Journal of emergency medicine, 49(4), 513–522.e1. https://doi.org/10.1016/j.jemermed.2014.12.080
[38] DiMartino, L. D., Baumann, A. A., Hsu, L. L., Kanter, J., Gordeuk, V. R., Glassberg, J., Treadwell, M. J., Melvin, C. L., Telfair, J., Klesges, L. M., King, A., Wun, T., Shah, N., Gibson, R. W., Hankins, J. S., & Sickle Cell Disease Implementation Consortium (2018). *The sickle cell disease implementation consortium: Translating evidence-based guidelines into practice for sickle cell disease.* American journal of hematology, 93(12), E391–E395. https://doi.org/10.1002/ajh.25282
[39] Glassberg, G., *Improving Emergency Department-Based Care of Sickle Cell Pain* (2017). Hematology. American Society of Hematology. Education Program, 2017(1), 412–417. https://doi.org/10.1182/asheducation-2017.1.412
[40] 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 30, 2024).

that of the national average,[41] with approximately 7,328 Medicaid enrollees with SCD per year. The study found that Florida's Medicaid SCD population was predominantly female (58%), young (median age 18), and Black (63%).

The study showed that nearly all of the Medicaid SCD population received treatment from a physician at least once during the study period. 85 percent of Medicaid SCD patients were evaluated or treated in an outpatient clinic setting, 61 percent were treated in an emergency room (ER) at least once, and 52 percent were admitted for inpatient care in a hospital. Individuals who received treatment in an ER had an average of 4.5 visits to the ER during the four-year study period.

The study showed that routine screenings and preventative treatments were broadly underutilized by the Medicaid SCD population. Only 41 percent of children in the Medicaid SCD population had at least one TCD screening for stroke risk during the four-year study period; this is significantly less than the recommended annual screening for children with SCD.[42] Data on blood transfusions, which are commonly used to reduce stroke risk when elevated risk is detected by TCD, were not included in the study.

The study showed that penicillin was the most commonly prescribed medication for Medicaid SCD patients. The study showed that 58 percent of eligible individuals were being prescribed penicillin, but there remains a persistent gap between use and recommended care. Other medications for treating SCD symptoms and complications were prescribed with even less frequency. Hydroxyurea[43] and L-glutamine were prescribed to only 22 percent and 2 percent of eligible SCD Medicaid patients respectively. The newer disease-modifying drugs, Voxelotor and Crizanlizumab were each prescribed to less than 1 percent of the eligible Medicaid SCD population.

Health Care Professional Licensure

The Division of Medical Quality Assurance (MQA), within the Department of Health (DOH), has general regulatory authority over health care practitioners.[44] The MQA works in conjunction with 22 professional boards and four councils to license and regulate seven types of health care facilities and more than 40 health care professions. Every profession is regulated by ch. 456, F.S., which provides general regulatory and licensure authority for the MQA, as well as a profession- or field-specific practice act which outlines requirements and standards that vary by profession and establishes the individual professional boards.

A professional board is a statutorily created entity that is authorized to exercise regulatory or rulemaking functions within the MQA.[45] Boards are responsible for approving or denying applications for licensure,[46] establishing continuing medical education requirements,[47] and are involved in disciplinary hearings.[48]

Continuing Education Requirements

General continuing education requirements for many health care practitioners, including those practitioners regulated by the Board of Medicine, the Board of Osteopathic Medicine, the Board of

[41] Centers for Medicare and Medicaid Services (2021), *Medicaid and CHIP Sickle Cell Disease Report, T-MSIS Analytic Files (TAF) 2017*. Available at https://www.medicaid.gov/medicaid/quality-of-care/downloads/scd-rpt-jan-2021.pdf (last visited January 31, 2024).
[42] *Supra*, note 17.
[43] AHCA cites high-cost as a potential barrier to the utilization of hydroxyurea by patients, however, it is worth noting that hydroxyurea is on Florida's preferred drug list for patients with SCD, which significantly reduces the cost.
[44] Pursuant to s. 456.001(4), F.S., health care practitioners are defined to include acupuncturists, physicians, physician assistants, chiropractors, podiatrists, naturopaths, dentists, dental hygienists, optometrists, nurses, nursing assistants, pharmacists, midwives, speech language pathologists, nursing home administrators, occupational therapists, respiratory therapists, dieticians, athletic trainers, orthotists, prosthetists, electrologists, massage therapists, clinical laboratory personnel, medical physicists, dispensers of optical devices or hearing aids, physical therapists, psychologists, social workers, mental health counselors, and psychotherapists, among others.
[45] S. 456.001(1), F.S.
[46] S. 456.013, F.S.
[47] *Id*.
[48] S. 456.072, F.S

Chiropractic Medicine, and the Board of Podiatric Medicine, are established under s. 456.013, F.S. As a condition of their biennial licensure renewal, these professions are required to periodically demonstrate their professional competency through the completion at least 40 hours of continuing education ever two years.[49]

Health care practitioners regulated by the Board of Nursing, specifically licensed practical nurses and registered nurses, and advanced practice registered nurses, may be required by the board to complete up to 30 hours of continuing education as a condition for biennial licensure renewal.[50]

In addition to the general continuing education requirements, current law requires some health care professions to complete continuing education courses covering specific subjects as a condition for licensure or certification renewal. The following subjects are required continuing education for specified health care practitioners:

- Human immunodeficiency virus (HIV) and acquired immune deficiency syndrome (AIDS);[51]
- Human trafficking;[52] and
- Domestic violence.[53]

It is the respective professional board's responsibility to approve specific continuing education courses that fulfill the statutory requirements. Failure of a licensee to comply with the continuing education requirements constitute grounds for disciplinary action.[54] In addition to discipline by the board, the licensee is required to complete the course.[55]

Effect of the Bill

CS/HB 349 requires health care practitioners licensed or certified under chapters 458, 459, and 464, F.S., to complete two hours of continuing education on the subject of sickle care disease management as a part of every second biennial licensure or certification renewal. The health care practitioners required to complete this continuing education course includes allopathic physicians, osteopathic physicians, physician assistants, anesthesiologist assistance, licensed practical nurses, registered nurses, and advanced practice registered nurses.

The required continuing education course may count toward a licensee's total number of required continuing education hours for those professionals required to complete 30 or more hours of continuing education biennially. The bill allows a professional holding two or more licenses subject to the requirements of the bill to satisfy such requirement through the completion of one board-approved course. Failure to comply with the requirements of the bill constitute grounds for disciplinary action by the appropriate professional board. In addition to discipline by the board, the bill requires that the licensee complete the required course.

The bill specifies that the course shall consist of education specific to SCD, including evidence-based treatment protocols for patients of all ages, continuing patient and family education, periodic comprehensive health evaluations and other disease-specific health maintenance services, psychosocial care, genetic counseling, and pain management.

[49] S. 456.013(6), F.S.
[50] S. 464.013, F.S.; Advanced practice registered nurses are required to complete at least three hours of continuing education on the safe and effective prescription of controlled substances as part of the 30-hour maximum.
[51] S. 456.033, F.S.; upon first licensure renewal, a one-hour course is required for health care practitioners licensed under ch. 457, ch. 458, ch. 459, ch. 460, ch. 461, ch. 463, part I of ch. 464, ch. 465, ch. 466, part II, part III, part V, or part X of ch. 468, and ch. 486, F.S.
[52] S. 456.0341, F.S.; A one-hour course is required for health care practitioners licensed under ch. 457, ch. 458, ch. 459, ch. 460, ch. 461, ch. 463, ch. 465, ch. 466, part II, part III, part V, or part X of ch. 468, ch. 480, and ch. 486, F.S.; *See also*, s. 464.013, F.S., licensed professional nurses, registered nurses, and advanced practice registered nurses are required to complete a two-hour course for every biennial licensure renewal.
[53] S. 456.031, F.S.; A two-hour course is required as part of every third biennial licensure or certification renewal for health care practitioners licensed under ch. 458, ch. 459, part I of ch. 464, ch. 466, ch. 467, ch. 490, and ch. 491, F.S.
[54] S. 456.072, F.S.
[55] Ss. 456.031 and 456.033, F.S.

The Board of Medicine, the Board of Osteopathic Medicine, and the Board of Nursing are responsible for implementing the provisions of the bill and approving appropriate continuing education courses. The bill authorizes each board to adopt rules to implement the provisions of the bill.

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

B. SECTION DIRECTORY:

Section 1: Creates s. 456.0311, F.S., relating to requirement for instruction on sickle cell disease.
Section 2: Provides an effective date of July 1, 2024.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None.

2. Expenditures:

The bill has an insignificant, negative fiscal impact on DOH associated with rulemaking necessary to implement the provisions of the bill, which can be absorbed within existing resources.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

None.

D. FISCAL COMMENTS:

None.

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 rule-making authority.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/COMMITTEE SUBSTITUTE CHANGES