FLORIDA HOUSE OF REPRESENTATIVES BILL ANALYSIS

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BILL #: CS/CS/CS/HB 1421

COMPANION BILL: CS/SB 890 (Yarborough)

TITLE: Improving Screening for and Treatment of Blood | **LINKED BILLS:** None

Clots

LINKED BILLS: None RELATED BILLS: None

SPONSOR(S): Black

Committee References
Health Professions & Programs

18 Y, 0 N, As CS

Health Care Budget 13 Y, 0 N, As CS

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Health & Human Services 23 Y, 0 N, As CS

SUMMARY

Effect of the Bill:

The bill creates the Emily Adkins Family Protection Act to improve screening and treatment measures for, and prevention of venous thromboembolism in Florida residents. The bill:

- Requires the Department of Health (DOH) to contract with a private entity who meets established criteria to create and maintain a statewide venous thromboembolism registry.
- Requires the Agency for Health Care Administration to submit a report to the Governor and the Legislature on the incidence of venous thromboembolisms using inpatient, outpatient, and ambulatory surgery data.
- Requires all hospitals with emergency departments to develop and implement policies and procedures for appropriate medical attention for persons at risk of forming venous thromboembolisms or deep vein thromboses (DVTs), which must reflect evidence-based best practices; and requires hospitals to train nonphysician personnel on their policies and procedures.
- Requires nursing homes and assisted living facilities (ALFs) to train personnel on how to recognize signs and symptoms of venous thromboembolism and DVT.
- Requires ALFs to provide consumer information pamphlets to residents containing certain information about venous thromboembolisms.

Fiscal or Economic Impact:

This bill requires DOH to contract with an entity to create the venous thromboembolism registry at no cost to the state; therefore, the bill has no fiscal impact on state government.

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EFFECT OF THE BILL:

Venous Thromboembolism Policy

The bill implements policy recommendations made by the <u>Florida Blood Clot and Pulmonary Embolism Policy</u> <u>Workgroup</u> to better identify, treat, and prevent <u>venous thromboembolism</u> (VTE) and <u>deep vein thrombosis</u> (<u>DVT</u>).

Statewide Venous Thromboembolism Registry

The bill requires the Department of Health (DOH) to contract with a private entity that meets certain established conditions to create and maintain, at no cost to the state, a statewide venous thromboembolism registry. Specifically, the private entity must:

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- Be a not-for-profit corporation;
- Have existed for at least 15 consecutive years with a mission of research and treatment of venous thromboembolism:
- Have experience with continuing education on venous thromboembolism;
- Have sponsored a public health education campaign on venous thromboembolism; and
- Be affiliated with a medical and scientific advisory board. (Section 4)

Beginning July 1, 2026, the bill requires each hospital with an emergency department (ED)to regularly report information to the registry containing nationally recognized performance measures and data on the incidence and prevalence of venous thromboembolisms, which must include:

- The number of venous thromboembolisms, and deep vein thromboses (DVTs) identified and diagnosed;
- The patient's age;
- The patient's zip code;
- The patient's sex;
- Whether the patient is a resident of a licensed nursing home or assisted living facility (ALF);
- Whether the venous thromboembolism, or DVT was fatal;
- How the diagnosis was made, such as by using imaging modalities; and
- The treatment that was recommended. (Section <u>4</u>)

The bill requires the private entity that is contracted by DOH to collect data for the registry, to also collect data on the above performance measures from each hospital with an emergency department. The bill prohibits the contractor from publishing information from the registry for any purpose other than advancing medical research or medical education in the interest of reducing morbidity or mortality. (Section $\underline{4}$)

The bill requires the Agency for Health Care Administration (AHCA) to submit a detailed report to the Governor and the Legislature, by June 1, 2026, on the incidence of venous thromboembolisms and pulmonary embolisms using inpatient, outpatient, and ambulatory surgery data for services provided between July 1, 2024 and June 30, 2025. The report must include:

- The age category, initial primary diagnosis and procedure, any secondary diagnoses, readmission rates for inpatients, admission rates for venous thromboembolism for which the patient had an ambulatory surgery procedure, and ED visits for venous thromboembolism linked to any previous admission.
- Whether the venous thromboembolism was present upon admission.
- The incidence of venous thromboembolisms for procedures reported on AHCA's Florida Health Finder website.
- The principal payor, the sex of the patient, and the patient's discharge status. (Section 4)

The bill requires all hospitals with EDs to develop and implement policies and procedures for the rendering of appropriate medical attention for persons at risk of forming venous thromboembolism or DVTs, which reflect evidence-based best practices relating to, at a minimum:

- Assessing patients for risk of venous thromboembolisms and DVTs using a nationally recognized risk assessment tool; and
- Treatment options for a patient diagnosed with a venous thromboembolism, or DVT. (Section 3)

Further, each hospital with an ED must train all nonphysician personnel at least annually on their policies and procedures. Nonphysician personnel includes all personnel working in clinical areas and providing patient care, but does not include licensed health care practitioners. (Section 3)

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Certified Nursing Assistant Training

In-Service Training

Under current law, a certified nursing assistant (CNA) employed by a nursing home for at least 12 months must undergo a performance review annually and receive regular in-service training based on the outcome of the performance reviews.

The bill requires the in-service training to now include training on recognizing signs and symptoms of a venous thromboembolism or DVT, and techniques for providing an emergency response. (Section 5)

Medication Administration

Under current law, a CNA may administer certain medications, upon delegation by a registered nurse, to patients in nursing homes if the CNA, among other things:

- Completes an initial 6-hour training course approved by the Board or AHCA; and
- Completes a 34-hour training course on medication administration and associated tasks including blood glucose level checks, dialing oxygen flow meters to prescribed settings, and assisting with continuous positive airway pressure devices.

The bill requires a CNA wishing to administer medication, as delegated by a registered nurse, to complete training on identifying signs and symptoms of venous thromboembolism, and response protocols to assist a patient with venous thromboembolism, as part of the 34-hour training course on medication administration. (Section 5)

Assisted Living Facilities

Minimum Standards for Resident Care

Current law requires AHCA to adopt reasonable and fair minimum standards relating to resident care in assisted living facilities (ALFs).

The bill requires these minimum standards to include standards for direct care staff on recognizing signs and symptoms of venous thromboembolism. (Section $\underline{6}$)

ALF Administrator Training Requirements

Under current law, an ALF administrator must pass a core competency test, within 90 days of employment, with a minimum passing score of 75 percent. The core competency test includes a variety of topics.

The bill requires the core competency test for ALF administrators to include, and ALF administrators to be tested on, recognizing signs and symptoms of venous thromboembolism. (Section 7)

Consumer Information Resources

The bill requires ALFs to provide a consumer information pamphlet to residents upon admission, which must contain information about risk factors for, and recognizing signs and symptoms of, venous thromboembolism. (Section 8)

Community Intervention Programs

The Chronic Diseases Act (ss. 385.101 – 385.103, F.S.) requires DOH to assist county health departments in developing and operating community intervention programs throughout the state to address one to three of the following chronic diseases: cancer, diabetes, heart disease, stroke, hypertension, renal disease, or chronic

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obstructive lung disease. The same diseases are listed in s. 385.102, F.S., of the Chronic Diseases Act, as part of legislative intent.

The bill adds chronic obstructive pulmonary disease, chronic critical illness, and genetic predisposition for developing venous thromboembolism to the list of diseases in s. 385.102, F.S., of the Chronic Diseases Act. Because this language is added to the legislative intent section of the Chronic Diseases Act, it has no substantive impact. (Section 2)

The effective date of the bill is July 1, 2025.

RULEMAKING:

AHCA will have to update rule 59A-36.007, F.A.C., to implement the requirement for ALF minimum standards of resident care to ensure direct care staff can recognize the signs and symptoms of venous thromboembolism.

AHCA will also have to update rule 59A-36.010, F.A.C., to revise the ALF administrator core competency test to include questions relating to venous thromboembolisms.

Lawmaking is a legislative power; however, the Legislature may delegate a portion of such power to executive branch agencies to create rules that have the force of law. To exercise this delegated power, an agency must have a grant of rulemaking authority and a law to implement.

FISCAL OR ECONOMIC IMPACT:

STATE GOVERNMENT:

The bill requires DOH to contract with a private entity to create the venous thromboembolism registry at no cost to the state. Therefore, there is no fiscal impact to state government.

RELEVANT INFORMATION

SUBJECT OVERVIEW:

Venous Thromboembolism

<u>Deep vein thrombosis (DVT)</u> is a blood clot located in a deep vein, usually in the leg or arm.¹ A pulmonary embolism (PE) occurs when part of the clot breaks off and travels to the lungs.² Venous thromboembolism (VTE) refers to DVT, PE, or both.

VTE affects an estimated 900,000 Americans each year, resulting in an estimated 100,000 deaths, the majority of which are due to sudden death from PE.³ These numbers are estimated because currently there is no systematic collection of VTE related morbidity or mortality data in the United States. The available information about disease prevalence and incidence consists of estimates based mainly on population-based epidemiologic studies and analysis of hospital discharge or health insurance claims databases. Such data supports the following findings:⁴

- One in four people who have a PE die without warning;
- More people die from a PE in the United States each year than from breast cancer, AIDS, and motor vehicle accidents combined.
- PEs are a leading cause of death in women during pregnancy or following delivery; and

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¹ Centers for Disease Control and Prevention, Impact of Blood Clots on the United States), available at https://www.cdc.gov/ncbddd/dvt/infographic-impact.html (last visited March 18, 2025).

² Id.

³ Giorgio K, Walker RF, MacLehose RF, et al. Venous thromboembolism mortality and trends in older US adults, 2011–2019. Am J Hematol 2023;98(9):1364–73.

⁴ Joseph Macchiavelli A. Venous Thromboembolism: *The Need for Transitions of Care. Med Clin North America* (September, 2023), available at https://pubmed.ncbi.nlm.nih.gov/37541714/ (last visited March18, 2025).

Blood clots are a leading cause of death in people with cancer.

Early diagnosis of a DVT is one of the most important factors in preventing a PE. The U.S. Department of Health and Human Services recommends that hospitals evaluate all patients upon admission and regularly thereafter.⁵ Those found to be at risk of developing a DVT should be given preventative treatment and medications.⁶

Causes

Thrombophilia is a condition that makes blood more likely to form clots. Thrombophilia can be inherited or acquired.7

In acquired thrombophilia, the abnormal clotting is related to a specific cause, such as prolonged periods of bed rest after surgery, long travel without standing and walking, trauma to the leg, or having cancer. Acquired thrombophilia is more common than inherited thrombophilia.8

Inherited thrombophilia is caused by gene mutations related to a genetic predisposition. The most common gene mutations are Factor V Leiden and Prothrombin G20210A.9

Factor V is a protein that is necessary for blood to clot properly. A factor V mutation, known as factor V Leiden, can be inherited from one or both parents. When you are injured, your body stops bleeding by changing liquid blood into a clot that blocks the leaks in damaged blood vessels. Factor V Leiden resists the body's natural process of turning off the clotting, which is why people with this mutation are more likely to form blood clots.¹⁰ Factor II Mutation is similar to Factor V Leiden, but it is slightly less common.

Five percent of Caucasians have Factor V Leiden, and it is more common in individuals of European ancestry, while one to two percent of African Americans, Hispanic Americans, and Native Americans have the mutation.¹¹

The Factor II Mutation is present in two to four percent of Caucasians, and it is also more common in individuals of European ancestry. Approximately 0.4 percent of African Americans have the mutation.¹²

Symptoms

The first signs of a PE are usually shortness of breath and chest pains, other symptoms include: 13

- Cough with or without bloody mucus;
- Pale, clammy or bluish skin;
- Rapid pulse;
- Excessive sweating;
- Wheezing: and
- In some cases, feeling anxious, lightheaded, faint or passing out.

Diagnosis and Treatment

https://www.stoptheclot.org/learn_more/prothrombin-g20210a-factor-ii-mutation/ (last visited March 18, 2025).

https://my.clevelandclinic.org/health/diseases/17400-pulmonary-embolism (last visited March 18, 2025).

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⁵ U.S. Department of Health and Human Services, The Surgeon General's Call to Action to Prevent Deep Vein Thrombosis and Pulmonary Embolism (2008), at pg. 20, available at https://www.ncbi.nlm.nih.gov/books/NBK44178/ (last visited March 18, 2025).

⁷ Cleveland Clinic, Health Library, Diseases and Conditions, Thrombophilia, available at https://my.clevelandclinic.org/health/diseases/21797-thrombophilia (last visited March 18, 2025).

⁸ Id.

⁹ Id. ¹⁰ Id.

¹¹ National Blood Clot Alliance, Factor V Leiden Information for Patients and Families, available at https://www.stoptheclot.org/learn_more/factor-v-leiden-2/ (last visited March 18, 2025).

¹² National Blood Clot Alliance, A Genetic Clotting Condition or Thrombophilia, available at

¹³ Cleveland Clinic, Pulmonary Embolism Symptoms, Signs, & Treatment, available at

The tests used to diagnose DVT depend on whether the patient is at a low or high risk of developing a DVT and include:14

- Duplex ultrasound This noninvasive test is the standard test for diagnosing DVT. A small hand-held device is moved over the body area being studied.
- D-dimer blood test D-dimer is a type of protein produced by blood clots, and almost all people with severe DVT have increased blood levels of D-dimer.
- Venography This invasive test uses X-rays and dye to create a picture of the veins in the legs and feet.
 The dye is injected into a large vein in the foot or ankle, which helps blood vessels show up more clearly on X-rays.

The goals of DVT treatment are preventing the clot from getting larger or from breaking loose and traveling to the lungs, and reducing the chances of DVT recurrence. DVT treatment includes: 16

- Blood thinners Also called anticoagulants, these medications help prevent blood clots from getting larger and reduce the risk of DVT recurrence.
- Clot busters Also called thrombolytics, these drugs are used for more serious cases of DVT or PE if other medications are not working.
- Filters Used for patients who cannot take blood thinners, a filter may be placed into a large vein in the abdomen to catch a blood clot that breaks loose and prevents it from lodging in the lungs.
- Support stockings Socks that help prevent blood from pooling in the legs and reduce swelling.

In certain high-risk groups of patients with VTE, alternative therapy or interventions may be indicated. For example, in a patient with a DVT, a large clot that obstructs blood flow and threatens the viability of the limb warrants more emergent intervention than therapeutic anticoagulation. In these cases, a thrombolytic medication may be administered to accelerate blood clot breakdown by catheter-directed thrombolysis inserted directly to the site of the DVT. In patients with an unacceptably high risk of bleeding or who fail to appropriately respond to thrombolytic therapy, mechanical extraction of the clot (thrombectomy) via a catheter or open surgery may be pursued.¹⁷

Blood Clot and Pulmonary Embolism Policy Workgroup

The Blood Clot and Pulmonary Embolism Policy Workgroup was created by the Legislature in 2023, to develop policy recommendations to improve standards of care, surveillance, detection, treatment, and patient and family education relating to blood clots and pulmonary embolisms.¹⁸

The Workgroup produced a final report with their policy recommendations in December of 2024. The Workgroup's policy recommendations include:19

- Implementing a statewide VTE monitoring system to collect data on VTE incidents across Florida, utilizing existing healthcare data infrastructure and integrating new data collection methods high priority.
- Standardizing VTE risk assessment protocols by mandating the use of standardized risk assessment tools (e.g., Wells Score²⁰ or Caprini Score²¹)in hospitals and healthcare facilities to identify patients at higher risk of developing VTE and ensure timely preventative measures are taken high priority.

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¹⁴ Mayo Clinic, *Deep Vein Thrombosis Diagnosis and Treatment*, available at https://www.mayoclinic.org/diseases-conditions/deep-vein-thrombosis/diagnosis-treatment/drc-20352563 (last visited March 18, 2025).

¹⁵ Id.

¹⁶ Id

¹⁷ Florida Blood Clot and Pulmonary Embolism Policy Workgroup, *Blood Clot and Pulmonary Embolism Policy Report* (December, 2024), available at https://ahca.myflorida.com/agency-administration/florida-center-for-health-information-and-transparency/office-of-data-collection-quality-assurance/blood-clot-and-pulmonary-embolism-policy-workgroup (last visited March 18, 2025).

¹⁸ Ch. 2023-192, Laws of Fla.

¹⁹ Supra note 14.

- Enhancing public awareness campaigns high priority.
- Improving post-discharge follow-up high priority.
- Incorporating surveying VTE prevention by monitoring for quality improvement into the Agency for Health Care Administration's (AHCA) facility surveying process.
- Improving diagnostic accuracy and timeless.
- Expanding awareness and care for VTE prevention for pregnant women and post-partum females.
- Expanding access to VTE preventative care.
- Establishing specialized VTE treatment centers.
- Recommending state support and promoting Florida centers and hospitals that specialize in VTE and chronic PE care.

Certified Nursing Assistant Training

In-Service Training

A CNA employed by a nursing home for at least 12 months must undergo a performance review annually and receive regular in-service education based on the outcome of the performance reviews. The in-service training must address:²²

- Techniques for assisting with eating and proper feeding;
- Techniques for assisting and responding to cognitively impaired residents;
- Principles of adequate nutrition and hydration; and
- Recognizing changes that place a resident at risk for pressure ulcers and falls.

Medication Administration

Under current law, a CNA may administer certain medications, upon delegation by a registered nurse, to patients in nursing homes if the CNA, among other things:²³

- Completes an initial 6-hour training course approved by the Board or AHCA; and
- Completes a 34-hour training course on medication administration and associated tasks including blood glucose level checks, dialing oxygen flow meters to prescribed settings, and assisting with continuous positive airway pressure devices.

Current law does not require a CNA to complete training on medication administration specific to blood clots.

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²⁰ The Wells Score objectifies a person's risk of pulmonary embolism based on a point system assigned to yes or no questions, including: clinical signs and symptoms of DVT; PE is #1 diagnosis or equally likely; heart rate > 100; immobilization at least three days or surgery in the previous four weeks; previous, objectively diagnosed PE or DVT; hemoptysis; and malignancy with treatment within six months or palliative. *See* https://www.mdcalc.com/calc/115/wells-criteria-pulmonary-embolism (last visited March 18, 2025).

²¹ The Caprini Score stratifies VTE risk in surgical patients based on: the patient's age, sex, and type of surgery; diagnosis of certain conditions in the last month including sepsis pneumonia, stroke, or hip, pelvis, or leg fracture, etc.; a diagnosis of venous disease or clotting disorder; mobility; and history of inflammatory bowel disease. *See* https://www.mdcalc.com/calc/3970/caprini-score-venous-thromboembolism-2005 (last visited March 18, 2025).

²² S. 400.211(4)(a), F.S.

²³ S. 400.211(5), F.S. A CNA must also hold a clear and active certification as a nursing assistant from DOH for at least one year immediately preceding the delegation of medication administration from a registered nurse, and demonstrate clinical competency by successfully completing a supervised clinical practice in medication administration and associated tasks in the facility.

Consumer Information Resources

Section 429.55, F.S., requires AHCA to include certain content on its website to help consumers make an informed decision when selecting an ALF for themselves or family members. Such content must include, among other things, the location of the facility, forms of accepted payment, the number of private and semi-private rooms offered, special services and activities provided, and a summary of violations committed during the previous 60 months.

Current law does not require AHCA to include information on its website about venous thromboembolisms, nor does it require ALFs to provide information to residents about venous thromboembolisms.

Assisted Living Facilities

An ALF is a residential establishment, or part of a residential establishment, that provides housing, meals, and one or more personal services for a period exceeding 24 hours to one or more adults who are not relatives of the owner or administrator. ALFs are licensed and regulated by AHCA under part I of ch. 429, F.S., and part II of ch. 408, F.S., and rule 59A-36, F.A.C.

ALF Minimum Standards for Resident Care

Section 429.41(1), F.S., requires AHCA to adopt reasonable and fair minimum standards relating to resident care, which must include:24

- Supervising residents;
- Providing personal services;
- Providing, or arranging for social and leisure activities;
- Assisting in arranging appointments and transportation to appropriate medical, dental, nursing, or mental health services:
- Managing medication as needed by residents;
- Accommodating dietary needs of residents; and
- Providing quality assurance through internal risk management.

Current law does not require ALFs to have minimum standards for resident care related to blood clots.

ALF Administrator Training Requirements

In addition to receiving training and meeting certain education requirements, an ALF administrator must pass a core competency test.²⁵ Administrators must pass the core competency test within 90 days of employment.²⁶ The minimum passing score for the test is 75 percent.²⁷

The core competency test must include the following topics:

- State law and rules relating to ALFs;
- Resident rights and identifying and reporting abuse, neglect, and exploitation;
- Special needs of elderly persons, persons with mental illness, and persons with developmental disabilities;
- Nutrition and food service, including acceptable sanitation practices for preparing, storing, and serving
- Medication management, recordkeeping, and proper techniques for assisting residents with selfadministered medication;
- Fire safety requirements, including fire evacuation drill procedures and other emergency procedures; and

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²⁴ S. 429.41(1)(g), F.S. The resident care standards are in rule 59A-36.007, F.A.C.

²⁵ S. 429.52(3), F.S.

²⁶ S. 429.52(4), F.S.

²⁷ Rule 59A-36.011, F.A.C.

• Caring for persons with Alzheimer's disease and related disorders.

Current law does not require the ALF administrator core competency test to measure an administrator's knowledge about blood clots.

RECENT LEGISLATION:

YEAR	BILL#	HOUSE SPONSOR(S)	SENATE SPONSOR	OTHER INFORMATION
2023	CS/SB 612	Black	Yarborough	Became law on July 1, 2023.

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			STAFF DIRECTOR/	ANALYSIS		
COMMITTEE REFERENCE	ACTION	DATE	POLICY CHIEF	PREPARED BY		
Health Professions & Programs	18 Y, 0 N, As CS	3/20/2025	McElroy	Guzzo		
<u>Subcommittee</u>						
THE CHANGES ADOPTED BY THE						
COMMITTEE:	12 V 0 N A c CC	4 (0 /2025	Clault	Dave		
Health Care Budget Subcommittee	13 Y, 0 N, As CS	4/9/2025	Clark	Day		
THE CHANGES ADOPTED BY THE COMMITTEE:						
<u>Health & Human Services</u> <u>Committee</u>	23 Y, 0 N, As CS	4/22/2025	Calamas	Guzzo		
THE CHANGES ADOPTED BY THE COMMITTEE:	 Moved the Statewide Venous Thromboembolism Registry from AHCA to DOH. Removed requirements for ASCs to report data to the registry. Removed the requirement for ALFs to have minimum standards of care for another facility's response protocols when treating an ALF resident. Required ALFs to have minimum standards of care to ensure that direct care staff can recognize signs and symptoms of venous thromboembolism. Required ALFs to provide consumer information pamphlets to residents which must include specified information on venous thromboembolisms. Revised the due date and reporting period dates for the report that AHCA must submit to the Governor and the Legislature on the incidence of venous thromboembolism. 					

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

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