# FLORIDA HOUSE OF REPRESENTATIVES BILL ANALYSIS

This bill analysis was prepared by nonpartisan committee staff and does not constitute an official statement of legislative intent.				
BILL #: <u>CS/HB 1421</u>	COMPANION BILL: <u>SB 890</u> (Yarborough)			
<b>TITLE:</b> Improving Screening for and Treatment of Blood	LINKED BILLS: None			
Clots	RELATED BILLS: None			
SPONSOR(S): Black				
Committee References				
Health Professions & Programs				
18 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 blood clots and pulmonary embolisms (PEs) in Florida residents. The bill:

- Adds blood clots and PEs to the Statewide Stroke Registry and requires certain health care facilities to report information containing certain nationally recognized blood clot and PE performance measures.
- Requires the Agency for Health Care Administration to submit a report to the Governor and the Legislature on the incidence of blood clots and PEs using inpatient, outpatient, and ambulatory surgery data.
- Requires all hospitals with emergency departments and ambulatory surgical centers to develop and implement policies and procedures for appropriate medical attention for persons at risk of forming blood clots, PEs, or DVTs, which must reflect evidence-based best practices; and requires hospitals and ASCs to train nonphysician personnel on their policies and procedures.
- Requires nursing homes and assisted living facilities to train personnel on how to recognize signs and symptoms of blood clots, PEs, and deep vein thrombosis.

### Fiscal or Economic Impact:

The bill will have a significant, negative fiscal impact on the Department of Health and no fiscal impact on local government.

JUMP TO	<b>SUMMARY</b>	ANALYSIS	<b>RELEVANT INFORMATION</b>	BILL HISTORY

## ANALYSIS

### **EFFECT OF THE BILL:**

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>blood clots and pulmonary embolisms</u> (PEs).

### Statewide Stroke and Blood Clot and PE Registry

The bill adds blood clots and PEs to the established <u>Statewide Stroke Registry</u> and requires certain health care facilities to report information containing certain nationally recognized blood clot and PE performance measures. Beginning July 1, 2026, the bill requires each hospital with an emergency department (ED) and each ambulatory surgical center (ASC) to regularly report information to the registry containing nationally recognized performance measures and data on the incidence and prevalence of blood clots and PEs, which must include:

- The number of blood clots, PEs, and <u>deep vein thromboses</u> (DVT) 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 blood clot, PE, or DVT was fatal;
- How the diagnosis was made, such as by using imaging modalities; and
- The treatment that was recommended. (Section 3)

The bill requires the private entity that is contracted by the Department of Health to collect data for the registry, to also collect data on the above performance measures from each hospital with an emergency department and ASCs. 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 3)

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

- The age category, initial primary diagnosis and procedure, any secondary diagnoses, readmission rates for inpatients, admission rates for blood clots and PEs for which the patient had an ambulatory surgery procedure, and ED visits for blood clots linked to any previous admission.
- Whether the blood clot or PE was present upon admission.
- The incidence of blood clots 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 3)

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

- Assessing patients for risk of blood clots, PEs, and DVTs using a nationally recognized risk assessment tool; and
- Treatment options for a patient diagnosed with a blood clot, PE, or DVT. (Section 4)

Further, each hospital with an ED and each ASC 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 4)

### **<u>Certified Nursing Assistant Training</u>**

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 blood clot, PE, or DVT, and techniques for providing an emergency response. (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 the identification of residents who are at risk for developing blood clots and the treating facility's response protocols to ensure access to timely treatment. (Section 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 for the test is 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, identifying and responding to residents at high risk of developing blood clots and PEs. (Section 7)

The effective date of the bill is July 1, 2025. (Section 8)

For purposes of diseases that are considered chronic diseases under s. 385.102, F.S., the bill adds chronic obstructive pulmonary disease, chronic critical illness, and genetic predisposition for developing blood clots and PEs. (Section 2)

#### **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 include identifying signs and symptoms of a blot clot and how to assist with a response protocol.

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 blood clots and PEs.

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 is expected to have a significant negative impact on DOH resulting from costs associated with adding blood clots and PEs to the Statewide Stroke Registry. The exact amount is unknown, however, DOH estimated the cost for the bill as filed to be from \$1 million to \$3 million to create a standalone registry for blood clots and PEs.

## **RELEVANT INFORMATION**

#### **SUBJECT OVERVIEW:**

### Statewide Stroke Registry

The Department of Health (DOH) maintains a statewide stroke registry with data submitted by stroke centers. The registry seeks to improve or modify the stroke care system, ensure compliance with standards and nationally

recognized guidelines, and improve patient outcomes.<sup>1</sup> Stroke centers must report information specified by DOH, including nationally recognized performance measures, to the registry. Stroke centers that do not comply with the reporting requirements are subject to licensure denial, modification, suspension, or revocation by AHCA.<sup>2</sup> Current law grants liability protection from damages or any other relief for any stroke center for providing the information required by the registry. Currently, the registry consists of 182 stroke centers and hospitals. The Florida Stroke Registry is maintained and managed by the University of Miami.<sup>3</sup>

### **Blood Clots and Pulmonary Embolisms**

<u>Deep vein thrombosis (DVT)</u> is a blood clot located in a deep vein, usually in the leg or arm.<sup>4</sup> A pulmonary embolism (PE) occurs when part of the clot breaks off and travels to the lungs.<sup>5</sup> 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.<sup>6</sup> 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:<sup>7</sup>

- 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
- 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.<sup>8</sup> Those found to be at risk of developing a DVT should be given preventative treatment and medications.<sup>9</sup>

### <u>Causes</u>

Thrombophilia is a condition that makes your blood more likely to form clots. Thrombophilia can be inherited or acquired.<sup>10</sup>

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.<sup>11</sup>

<sup>4</sup> 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).

<sup>&</sup>lt;sup>1</sup> S. 395.30381, F.S.

<sup>&</sup>lt;sup>2</sup> S. 395.003(7)(a), F.S., authorizes AHCA to deny, modify, suspend, and revoke a license for the substantial failure to comply with any requirements of Part I of Chapter 395, F.S.

<sup>&</sup>lt;sup>3</sup> Miami University, Miller School of Medicine, Florida Stroke Registry, available at

<sup>&</sup>lt;u>https://med.miami.edu/departments/neurology/research/the-florida-stroke-collaboration/florida-stroke-registry</u> (last visited March 18, 2025).

<sup>&</sup>lt;sup>5</sup> Id.

<sup>&</sup>lt;sup>6</sup> 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.

<sup>&</sup>lt;sup>7</sup> Joseph Macchiavelli A. Venous Thromboembolism: *The Need for Transitions of Care. Med Clin North America* (September, 2023), available at <u>https://pubmed.ncbi.nlm.nih.gov/37541714/</u> (last visited March18, 2025).

 <sup>&</sup>lt;sup>8</sup> 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 <a href="https://www.ncbi.nlm.nih.gov/books/NBK44178/">https://www.ncbi.nlm.nih.gov/books/NBK44178/</a> (last visited March 18, 2025).
 <sup>9</sup> Id.

<sup>&</sup>lt;sup>10</sup> Cleveland Clinic, Health Library, Diseases and Conditions, Thrombophilia, available at <u>https://my.clevelandclinic.org/health/diseases/21797-thrombophilia</u> (last visited March 18, 2025).

<sup>&</sup>lt;sup>11</sup> Id.

Inherited thrombophilia is caused by gene mutations related to a <u>genetic predisposition</u>. The most common gene mutations are Factor V Leiden and Prothrombin G20210A.<sup>12</sup>

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.<sup>13</sup> 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.<sup>14</sup>

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.<sup>15</sup>

### <u>Symptoms</u>

The first signs of a PE are usually shortness of breath and chest pains, other symptoms include:<sup>16</sup>

- 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**

The tests used to diagnose DVT depend on whether the patient is at a low or high risk of developing a DVT and include:<sup>17</sup>

- 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.<sup>18</sup> DVT treatment includes:<sup>19</sup>

<sup>&</sup>lt;sup>12</sup> Id.

<sup>&</sup>lt;sup>13</sup> Id.

<sup>&</sup>lt;sup>14</sup> 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).

<sup>&</sup>lt;sup>15</sup> National Blood Clot Alliance, A Genetic Clotting Condition or Thrombophilia, available at

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

<sup>&</sup>lt;sup>16</sup> Cleveland Clinic, Pulmonary Embolism Symptoms, Signs, & Treatment, available at

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

<sup>&</sup>lt;sup>17</sup> Mayo Clinic, *Deep Vein Thrombosis Diagnosis and Treatment*, available at <u>https://www.mayoclinic.org/diseases-conditions/deep-vein-thrombosis/diagnosis-treatment/drc-20352563</u> (last visited March 18, 2025).

<sup>&</sup>lt;sup>18</sup> Id. <sup>19</sup> Id.

- 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.<sup>20</sup>

## 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.<sup>21</sup>

The Workgroup produced a final report with their policy recommendations in December of 2024. The Workgroup's policy recommendations include:<sup>22</sup>

- 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 Score<sup>23</sup> or Caprini Score<sup>24</sup>)in hospitals and healthcare facilities to identify patients at higher risk of developing VTE and ensure timely preventative measures are taken high priority.
- 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.

## **<u>Certified Nursing Assistant Training</u>**

<sup>&</sup>lt;sup>20</sup> Florida Blood Clot and Pulmonary Embolism Policy Workgroup, *Blood Clot and Pulmonary Embolism Policy Report* (December, 2024), available at <u>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).</u>

<sup>&</sup>lt;sup>21</sup> Ch. 2023-192, Laws of Fla.

<sup>&</sup>lt;sup>22</sup> Supra note 14.

<sup>&</sup>lt;sup>23</sup> 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).

<sup>&</sup>lt;sup>24</sup> 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* <u>https://www.mdcalc.com/calc/3970/caprini-score-venous-thromboembolism-2005</u> (last visited March 18, 2025).

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:<sup>25</sup>

- 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.

### **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:<sup>26</sup>

- 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.<sup>27</sup> Administrators must pass the core competency test within 90 days of employment.<sup>28</sup> The minimum passing score for the test is 75 percent.<sup>29</sup>

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 food;
- 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

<sup>27</sup> S. 429.52(3), F.S.

<sup>28</sup> S. 429.52(4), F.S.
<sup>29</sup> Rule 59A-36.011, F.A.C.

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<sup>&</sup>lt;sup>25</sup> S. 400.211(4)(a), F.S.

<sup>&</sup>lt;sup>26</sup> S. 429.41(1)(g), F.S. The resident care standards are in rule 59A-36.007, 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	<u>CS/SB 612</u>	Black	Yarborough	Became law on July 1, 2023.

BILL HISTORY							
COMMITTEE REFERENCE	ACTION	DATE	STAFF DIRECTOR/ POLICY CHIEF	ANALYSIS PREPARED BY			
<u>Health Professions &amp; Programs</u> <u>Subcommittee</u>	18 Y, 0 N, As CS	3/20/2025	McElroy	Guzzo			
THE CHANGES ADOPTED BY THE COMMITTEE:	Click or tap here to ente	er text.					

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

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