

The Florida Senate
BILL ANALYSIS AND FISCAL IMPACT STATEMENT

(This document is based on the provisions contained in the legislation as of the latest date listed below.)

Prepared By: The Professional Staff of the Appropriations Committee on Health and Human Services

BILL: CS/SB 890

INTRODUCER: Appropriations Committee on Health and Human Services and Senator Yarborough and others

SUBJECT: Improving Screening for and Treatment of Blood Clots

DATE: April 17, 2025

REVISED: _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	<u>Looke</u>	<u>Brown</u>	<u>HP</u>	<u>Favorable</u>
2.	<u>Gerbrandt</u>	<u>McKnight</u>	<u>AHS</u>	<u>Fav/CS</u>
3.	<u> </u>	<u> </u>	<u>FP</u>	<u> </u>

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/SB 890 amends current law to create the Emily Adkins Family Protection Act to improve screening for and treatment of blood clots. Specifically, the bill:

- Specifies that chronic critical illness and genetic predisposition for developing venous thromboembolisms (VTE) are chronic diseases.
- Requires specified training and protocols to assess and treat patients at risk of VTE when the patient is admitted to a hospital with an emergency room or ambulatory surgical center (ASC).
- Requires the Agency for Health Care Administration's (AHCA) to contract with a private entity to establish and maintain a statewide VTE registry (registry).
- Requires each hospital with an emergency department and each ASC to report certain information to the registry.
- Requires certified nursing assistants (CNA) serving in a nursing home to receive training on recognizing the signs and symptoms of VTE and techniques for providing an emergency response.
- Requires the AHCA rules for assisted living facilities (ALF) to include requirements for the identification of residents at risk for developing VTE and for the treating facility's response protocols to ensure timely treatment.
- Requires the AHCA to include training on the identification of and response to residents at high risk of developing blood clots and pulmonary embolisms in the core training required for all ALF administrators.

The bill has no fiscal impact on state revenues or expenditures. **See Section V., Fiscal Impact Statement.**

The bill takes effect July 1, 2025.

II. Present Situation:

Blood Clots

Blood clotting, or coagulation, is an important process that prevents excessive bleeding when a blood vessel is injured. Platelets (a type of blood cell) and proteins in plasma (the liquid part of blood) work together to stop the bleeding by forming a clot over the injury. Typically, the human body will naturally dissolve the blood clot after the injury has healed.

Sometimes, however, blood clots form on the inside of vessels without an obvious injury or do not dissolve naturally. These situations can be dangerous and require accurate diagnosis and appropriate treatment.

Clots can occur in veins or arteries, which are vessels that are part of the body's circulatory system. While both types of vessels help transport blood throughout the body, they each function differently. Veins are low-pressure vessels that carry deoxygenated blood away from the body's organs and back to the heart. An abnormal clot that forms in a vein may restrict the return of blood to the heart and can result in pain and swelling as the blood gathers behind the clot.

Deep Vein Thrombosis (DVT) is a type of clot that forms in a major vein of the leg or, less commonly, in the arms, pelvis, or other large veins in the body. In some cases, a clot in a vein may detach from its point of origin and travel through the heart to the lungs where it becomes wedged, preventing adequate blood flow. This is called a pulmonary (lung) embolism and can be extremely dangerous.

It is estimated that each year DVT affects as many as 900,000 people in the United States and kills up to 100,000.¹

Blood Clots and Genetics

Thrombophilia is a medical term used to describe the condition where the blood has an increased tendency to clot. There are many reasons why the blood can have this increased tendency. Thrombophilia is usually categorized into two types—acquired and inherited. In acquired thrombophilia the abnormal clotting is usually related to a specific cause, such as prolonged periods of bed rest after surgery, trauma to the leg, or having cancer. People with inherited thrombophilia tend to form clots due to a genetic predisposition inherited from their parents. People with inherited thrombophilia may have a family history of relatives with abnormal or excessive blood clotting.

¹ American Society of Hematology, *Blood Clots*, available at <https://www.hematology.org/education/patients/blood-clots>, (last visited March 7, 2025).

Blood clotting proteins, like all proteins, are made by linking together a chain of chemicals called amino acids. The order of the amino acids in the chain make up a specific protein; this order is determined by genes. While there are a number of mutations that can cause inherited thrombophilia, the most common deoxyribose nucleic acid (DNA) mutations are named factor V Leiden and prothrombin G20210A.²

Factor V Leiden

Human bodies produce a protein called factor V that helps blood clot. However, there are certain individuals who have a DNA mutation in the gene used to make the factor V protein. These individuals are said to have the “factor V Leiden” mutation.

Normally the factor V protein is produced to help the blood clot and is produced in greater amounts after a blood vessel is damaged. The amount of factor V protein produced is controlled by other proteins, including protein C and protein S. Protein C and protein S combine to help break up factor V, thus preventing it from being reused and clotting the blood.

When a person has factor V Leiden, the mutation causes the protein to be abnormally shaped. This abnormal shape prevents it from being broken down properly by proteins C and S. Since the factor V protein is not broken down, it is left in the blood for a longer period of time and increases the tendency for clotting.

It is estimated that about five percent of Caucasians have factor V Leiden, and it is more common in individuals of European ancestry. In the United States, approximately one to two percent of African Americans, Hispanic Americans, and Native Americans also have the mutation. Factor V Leiden is rare in people of Asian decent.³

Prothrombin G20210A Mutation

All individuals make the prothrombin (also called factor two) protein that helps blood clot. However, there are certain individuals who have a DNA mutation in the gene used to make prothrombin called the prothrombin G20210A or the factor II mutation.

Normally, the prothrombin protein is produced to help the blood clot and is produced in greater amounts after a blood vessel is damaged. People who have a mutation in the prothrombin gene produce more prothrombin protein than is normal. Since there is more of the prothrombin protein in the blood, this increases the tendency for clotting.

A change in the prothrombin gene is present in two to four percent of Caucasians and is more common in individuals of European ancestry. In the United States, approximately 0.4 percent of African Americans also have the mutation. Prothrombin G20210A mutation is rare in other demographic groups.

² National Blood Clot Alliance, *The Genetics of Thrombophilia*, Elizabeth Varga, available at <https://www.stoptheclot.org/about-clots/thrombophilia/genetics-of-thrombophilia/>, (last visited March 7, 2025).

³ Id.

Deep Vein Thrombosis

DVT occurs when a blood clot (thrombus) forms in one or more of the deep veins in the body, usually in the legs. Deep vein thrombosis can cause leg pain or swelling. Sometimes there are no noticeable symptoms.

Persons can get DVT if they have certain medical conditions that affect how the blood clots. A blood clot in the legs can also develop if a person doesn't move for a long time, e.g. sitting for an extended period while traveling a long distance or when a person is on bed rest due to surgery, an illness, or an accident.

Deep vein thrombosis can be serious because blood clots in the veins can break loose. The clots can then travel through the bloodstream and get stuck in the lungs, blocking blood flow (pulmonary embolism). When DVT and pulmonary embolism occur together, it's called venous thromboembolism (VTE).

Many things can increase the risk of developing DVT. The more risk factors are involved, the greater the risk of DVT. Risk factors for DVT include:

- **Age.** Being older than 60 increases the risk of DVT, but DVT can occur at any age.
- **Lack of movement.** Muscle contractions help blood flow. Sitting for a long time, such as when driving or flying, increases the risk of DVT. So does long-term bed rest, which may result from a lengthy hospital stay or a medical condition such as paralysis.
- **Injury or surgery.** Injury to the veins or surgery can increase the risk of blood clots.
- **Pregnancy.** Pregnancy increases the pressure in the veins in the pelvis and legs. The risk of blood clots from pregnancy can continue for up to six weeks after a baby is born. People with an inherited clotting disorder are especially at risk.
- **Birth control pills (oral contraceptives) or hormone replacement therapy.** Both can increase the blood's ability to clot.
- **Being overweight or obese.** Being overweight increases the pressure in the veins in the pelvis and legs.
- **Smoking.** Smoking affects how blood flows and clots, which can increase the risk of DVT.
- **Cancer.** Some cancers increase substances in the blood that cause the blood to clot. Some types of cancer treatment also increase the risk of blood clots.
- **Heart failure.** Heart failure increases the risk of DVT and pulmonary embolism.
- **Inflammatory bowel disease.** Crohn's disease or ulcerative colitis increase the risk of DVT.
- **A personal or family history of DVT or pulmonary embolism.** A person with a family history of these conditions might be at greater risk of developing DVT.
- **Genetics.** Some people have DNA changes that cause the blood to clot more easily.⁴

III. Effect of Proposed Changes:

The bill makes changes related to blood clots.

Section 1 names the act as the “Emily Adkins Family Protection Act.”

⁴ Mayo Clinic, *Deep Vein Thrombosis*, June 11, 2022, available at <https://www.mayoclinic.org/diseases-conditions/deep-vein-thrombosis/symptoms-causes/syc-20352557>, (last visited March 7, 2025).

Section 2 amends s. 385.102, F.S., relating to the list of chronic diseases⁵ that exist in high proportions among people of this state, to add “chronic critical illness,” and “genetic predisposition for developing venous thromboembolism (VTE) .” The bill also updates the term “chronic obstructive lung disease” to “chronic obstructive pulmonary disease.”

Section 3 amends s. 395.1012, F.S., relating to patient safety, to require each hospital with an emergency department and each ambulatory surgical center to:

- Develop and implement policies and procedures for the rendering of appropriate medical attention for persons at risk of forming VTE which reflect evidence-based best practices relating to, at a minimum:
 - Assessing patients for risk of VTE using a nationally recognized risk assessment tool.
 - Treatment options for a patient diagnosed with VTE.
- Train all nonphysician personnel at least annually on the policies and procedures developed under this subsection. For purposes of this subsection, “nonphysician personnel” means all personnel of the licensed facility working in clinical areas and providing patient care, except those persons licensed as health care practitioners.

Section 4 creates s. 395.3042, F.S., to require the Agency for Health Care Administration to contract with a private entity to establish and maintain, at no cost to the state, a statewide VTE registry (registry) to ensure that the performance measures that are required to be submitted are maintained and available for use to improve or modify the VTE care system, ensure compliance with nationally recognized guidelines, and monitor patient outcomes. The private entity must:

- Have existed for at least 15 consecutive years with a mission of advancing the prevention, early diagnosis, and successful treatment of blood clots.
- Have experience operating a medical registry with at least 25,000 participants.
- Have experience in providing continuing education on VTE to medical professionals.
- Have sponsored a public health education campaign on VTE.
- Be affiliated with a medical and scientific advisory board.

The bill requires each hospital with an emergency department and each ambulatory surgical center to report to the registry the following measures and data on the incidence and prevalence of VTE:

- The number of VTE identified and diagnosed.
- The age of the patient.
- The zip code of the patient.
- The sex of the patient.
- Whether the patient is a resident of a licensed nursing home or assisted living facility.
- Whether the VTE was fatal.
- How the diagnosis was made, such as by using imaging modalities.
- The treatment that was recommended for the VTE.

The bill requires the contracted private entity to use a nationally recognized platform to collect data from each reporting entity and to provide regular reports on the data to the AHCA.

⁵ The list contains diseases that must be included as chronic diseases under ch. 385, F.S., but is not exclusive.

The bill specifies that the DOH, or the contractor operating the registry, may use or publish information from the registry only for the purpose of advancing medical research or medical education in the interest of reducing morbidity or mortality, except that a de-identified summary of the information contained in the registry may be released for general publication.

By March 1, 2026, the AHCA must submit a report to the Governor, the President of the Senate, and the Speaker of the House of Representatives a report on the incidence of VTE using inpatient, outpatient, and ambulatory surgical center data for services provided between July 1, 2024, and July 1, 2025. The report must analyze the following:

- Age category, initial primary diagnosis and procedure, and secondary diagnoses, readmission rates for inpatients, admission rates for VTE for which the patient had an ambulatory surgery procedure, and emergency department visits for VTE linked to any previous admission.
- Whether the VTE was present upon admission.
- The incidence of VTE procedures reported on the agency's Florida Health Finder website.
- The principal payor, the sex of the patient, and the patient's discharge status.

The bill allows the private entity operating the registry to use and publish the information from the registry only for the purposes the advancing medical research and medical education.

Section 5 amends s. 400.211, F.S., to require that a nursing home's in-service training for certified nursing assistants (CNA) must include recognizing signs and symptoms of VTE and techniques for providing emergency response. The bill requires that the identification of signs and symptoms of VTE and how to assist with a response protocol must be included in the required training a CNA must have in order for a registered nurse to delegate duties to him or her.

Sections 6 and 7 amend ss. 429.41 and 429.52, F.S., respectively, to require rules regulating assisted living facilities (ALF) to include standards for the identification of residents who are at risk for developing VTE and the treating facility's response protocols to help ensure access to timely treatment, and to require core training for ALF administrators to include identification of and responding to residents at high risk of developing blood clots and pulmonary embolisms.

The bill takes effect July 1, 2025.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

D. State Tax or Fee Increases:

None.

E. Other Constitutional Issues:

None.

V. Fiscal Impact Statement:**A. Tax/Fee Issues:**

None.

B. Private Sector Impact:

CS/SB 890 may have an indeterminate, negative fiscal impact on hospital with an emergency department and each ambulatory surgical center which are required under the bill to report specified information to the venous thromboembolism registry created by the bill and adopt new training, policies, protocols, or procedures.

C. Government Sector Impact:

The bill requires the Agency for Health Care Administration to contract with a private entity to establish and maintain, at no cost to the state, the venous thromboembolism registry, therefore, the bill has no fiscal impact on state expenditures.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill substantially amends the following sections of the Florida Statutes: 385.102, 395.1012, 400.211, 429.41, and 429.52.

This bill creates section 395.3042 of the Florida Statutes.

IX. Additional Information:**A. Committee Substitute –Statement of Substantial Changes:**

(Summarizing differences between the Committee Substitute and the prior version of the bill.)

CS by Appropriations Committee on Health and Human Services on April 15, 2025:

The committee substitute:

- Names the act as the “Emily Adkins Family Protection Act.”

- Replaces provisions in the underlying bill specifying one or more of blood clots, deep vein thrombosis (DVT), or pulmonary embolisms with the term “venous thromboembolism (VTE).”
- Revises requirements in the underlying bill related to specified training and care for the treatment of blood clots, pulmonary embolisms, or DVT with a provision requiring hospitals and ASCs to develop policies and procedures for best practices for treating persons with VTE and specifies that nonphysician personnel must be trained at least annually on such policies and procedures.
- Revises the blood clot and pulmonary embolism registry in the underlying bill into the statewide VTE registry by requiring the Agency for Health Care Administration (AHCA) to contract with a private entity meeting specified requirements to establish and maintain the registry, at no cost to the state.
- Specifies the data that must be submitted to the registry and that the private entity must provide regular reports on the data to the AHCA.
- Requires the AHCA to submit a report to the Governor and the Legislature on incidence of VTE in Florida by March 1, 2026.

B. Amendments:

None.