# 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.)

Prepar	ed By: The Pi	rofessional S	taff of the Appro	opriations Committe	e on Health and Human Services
BILL:	SB 890				
INTRODUCER:	Senator Yarborough				
SUBJECT:	Improving Screening for and Treatment of Blood Clots				
DATE:	April 14, 2	2025	REVISED:		
ANALYST		STAFF DIRECTOR		REFERENCE	ACTION
Looke		Brown		HP	Favorable
2. Gerbrandt		McKnight		AHS	Pre-meeting
3.				FP	

# I. Summary:

SB 890 amends current law to improve screening for and treatment of blood clots. Specifically, the bill:

- Specifies that chronic critical illness and genetic predisposition for developing blood clots and pulmonary embolisms are chronic diseases.
- Requires the Department of Health (DOH) to create a blood clot and pulmonary embolism registry;
- Requires specified training and protocols to screen a patient for the risk of blood clots, pulmonary embolism, or deep vein thrombosis (DVT) when the patient is admitted to a hospital or ambulatory surgical center (ASC) that provides specified services;
- Requires certified nursing assistants (CNA) serving in a nursing home to receive training on recognizing the signs and symptoms of a blood clot, pulmonary embolism, or DVT and techniques for providing an emergency response;
- Requires the Agency for Health Care Administration's (AHCA) rules for assisted living facilities (ALF) to include requirements for the identification of residents at risk for developing blood clots and for the treating facility's response protocols to ensure timely treatment; and
- 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 a significant, negative fiscal impact on state revenues and 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.

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

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

thrombophilia, the most common deoxyribose nucleic acid (DNA) mutations are named factor V Leiden and prothrombin G20210A.<sup>2</sup>

# 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.<sup>3</sup>

# 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.

# **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.

<sup>&</sup>lt;sup>2</sup> National Blood Clot Alliance, *The Genetics of Thrombophilia*, Elizabeth Varga, available at <a href="https://www.stoptheclot.org/about-clots/thrombophilia/genetics-of-thrombophilia/">https://www.stoptheclot.org/about-clots/thrombophilia/genetics-of-thrombophilia/</a>, (last visited March 7, 2025). <sup>3</sup> Id.

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.<sup>4</sup>

# III. Effect of Proposed Changes:

The bill makes changes related to blood clots.

**Section 1** amends s. 385.102, F.S., relating to the list of chronic diseases<sup>5</sup> that exist in high proportions among people of this state, to add "chronic critical illness" and "genetic predisposition for developing blood clots and pulmonary embolisms." The bill also updates the term "chronic obstructive lung disease" to "chronic obstructive pulmonary disease."

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

<sup>&</sup>lt;sup>5</sup> The list contains diseases that must be included as chronic diseases under ch. 385, F.S., but is not exclusive.

**Section 2** creates s. 385.213, F.S., to require the Department of Health (DOH) to establish, or contract with a recognized medical organization in Florida and its affiliated institutions, to establish a statewide blood clot and pulmonary embolism registry (registry) to ensure that blood clot and pulmonary embolism reports are maintained and available for use in the course of research for the purpose of reducing morbidity and mortality. The bill specifies that hospitals are immune from liability for having provided information to the DOH for inclusion in the registry.

The bill requires each facility licensed under chs. 395<sup>6</sup> or 408,<sup>7</sup> F.S., to report to the DOH the following information for each instance of a blood clot, pulmonary embolism, or deep vein thrombosis (DVT) identified in a patient:

- The number of blood clots, pulmonary embolisms, and deep vein thromboses 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 blood clot, pulmonary embolism, or deep vein thrombosis was fatal.
- How the diagnosis was made, such as by using imaging modalities.
- The treatment that was recommended for the blood clot, pulmonary embolism, or deep vein thrombosis, as applicable.

The bill allows the DOH, by rule, to further specify what information is to be provided.

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.

The bill also creates a public records exemption, making the records confidential and exempt, for personal identifying information held in the registry, except that:

- Such information may be released with the express written consent of the person or his or her legally authorized representative;
- The DOH or the contractor may contact individuals for the purpose of epidemiologic investigation and monitoring, provided such information that is confidential is not further disclosed; and
- The DOH may exchange data that includes personal identifying information with any other governmental agency or the contractor for the purpose of medical or scientific research, provided such governmental agency or contractor does not further disclose information that is confidential and exempt.

The bill specifies that any funds appropriated for implementation of the registry must be used for establishing, administering, compiling, processing, and providing biometric and statistical analyses to the reporting facilities. Funds may also be used to ensure the quality and accuracy of the information reported and to provide management information to the reporting facilities.

<sup>&</sup>lt;sup>6</sup> Hospitals and ambulatory surgical centers.

<sup>&</sup>lt;sup>7</sup> The list of facility types licensed pursuant to ch. 408, F.S., is in s. 408.802, F.S.

The bill allows the DOH, by rule, to classify facilities for purposes of reports made to the registry and specify the content and frequency of the reports. In classifying facilities, the DOH must exempt certain facilities from reporting blood clot and pulmonary embolism information that was previously reported to the DOH or retrieved from existing state reports made to the DOH or the Agency for Health Care Administration (AHCA).

The bill also exempts any facility from reporting to the registry if the primary purpose of the facility is to provide psychiatric care.

**Section 3** creates s. 395.3042, F.S., to require hospitals and ambulatory surgical centers that provide emergency room services, orthopedic services, pregnancy services, or cancer treatment, to arrange for the rendering of appropriate medical attention for persons at risk for blood clots, pulmonary embolisms, or DVT as follows:

- Upon admission to such a facility, a patient must be assessed for risk of blood clots, pulmonary embolisms, and DVT using a nationally recognized risk assessment tool.
- The training of all staff in the facility must include continuing education annually on how to recognize a blood clot, pulmonary embolism, or DVT.
- The facility must have established protocols for staff to ensure that patients diagnosed with a life-threatening blood clot, pulmonary embolism, or DVT are assessed for various treatment options.
- The facility must have an established policy in place requiring a follow-up for all orthopedic
  patients who have undergone lower extremity or pelvic surgery, to occur within 60 days after
  discharge.
- The facility must have procedures in place to provide ongoing blood clot risk assessment for patients who are at high risk of developing blood clots, are pregnant, or are being treated for cancer.

**Section 4** 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 a blood clot, pulmonary embolism, or DVT and techniques for providing emergency response. The bill requires that the identification of signs and symptoms of a blood clot 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 5 and 6** 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 blood clots 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:

Article I, Sectio 24(c), of the Florida Constitution requires that any law enacting a new public records exemption contain "only exemptions from [public records and meetings requirements], and shall relate to one subject." Additionally, any law enacting a new public records exemption "shall state with specificity the public necessity justifying the exemption."

Section 2 creates a new public records exemption for records held in the blood clot and pulmonary embolism registry. However, this public records exemption is created within a bill that contains other items and does not relate only to that public records exemption. Additionally, the bill does not specifically state the public necessity for the public records exemption. As such, it is possible that the public records exemption created by the bill may be found to be unconstitutionally enacted, should the bill be enacted.

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:

SB 890 may have an indeterminate, negative fiscal impact on facilities licensed under ch. 395, F.S., or ch. 408, F.S., which are required under the bill to report specified information to the blood clot and pulmonary embolism registry created by the bill and adopt new training, policies, protocols, or procedures.

# C. Government Sector Impact:

According to the Department of Health (DOH), the bill requires additional staff and data infrastructure resources to include blood clot and pulmonary embolism data into a statewide registry. The cost of such resources is estimated at \$2,000,000. The DOH will also incur nonrecurring costs for rulemaking, which can be absorbed within existing resources.<sup>8</sup>

#### VI. Technical Deficiencies:

None.

# VII. Related Issues:

Section 2 creates the blood clot and pulmonary embolism registry (registry) within the Department of Health (DOH). The bill requires that all facilities licensed with the Agency for Health Care Administration (AHCA) under ch. 408, F.S., provide specified information to the DOH. However, the bill only exempts hospitals from liability for providing such information. It may be advisable to extend liability protection to all facility types that are required to provide information under the bill. Additionally, it is unclear how some facilities licensed under ch. 408, F.S., such as nurse registries and home medical equipment providers, would be able to comply with the requirement to provide the specified information. The bill allows the DOH, by rule, to classify and exempt certain facilities from the bill's reporting requirements, but it is unclear whether this rulemaking authority would be sufficient to allow the DOH to exempt other types of facilities not listed in the bill.

**Section 2** specifies that any funds appropriated for the implementation of the registry must be used for "establishing, administering, compiling, processing, and providing biometric and statistical analyses to the reporting facilities." Given the large quantity and the multiple types of facilities required to report, it is unclear whether such reporting would be practical.

**Section 3** requires that certain hospitals and ambulatory surgical centers (ASC) provide specified training and create specified policies, protocols, and procedures related to blood clots, pulmonary embolisms, and deep vein thrombosis (DVT). However, the bill does not specify the time frame in which such training, policies, protocols, and procedures must be adopted. It may be advisable to allow hospitals and ASCs a specific amount of time to put such training, policies, protocols, and procedures in place prior to requiring them.

# VIII. Statutes Affected:

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

This bill creates the following sections of the Florida Statutes: 385.213 and 395.3042.

<sup>&</sup>lt;sup>8</sup> Department of Health, 2025 Agency Legislative Bill Analysis, HB 1421 (April 2, 2025) (on file with the Senate Appropriations Committee on Health and Human Services).

#### IX. **Additional Information:**

Committee Substitute – Statement of Changes: (Summarizing differences between the Committee Substitute and the prior version of the bill.) A.

None.

B. Amendments:

None.

This Senate Bill Analysis does not reflect the intent or official position of the bill's introducer or the Florida Senate.