

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 Committee on Fiscal Policy

BILL: CS/SB 612

INTRODUCER: Health Policy Committee and Senator Yarborough and others

SUBJECT: Blood Clot and Pulmonary Embolism Policy Workgroup

DATE: April 19, 2023 **REVISED:** _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	<u>Stovall</u>	<u>Brown</u>	<u>HP</u>	Fav/CS
2.	<u>McKnight</u>	<u>Money</u>	<u>AHS</u>	Favorable
3.	<u>Stovall</u>	<u>Yeatman</u>	<u>FP</u>	Pre-meeting

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/SB 612 creates the “Emily Adkins Prevention Act” to establish a blood clot and pulmonary embolism policy workgroup. The Secretary of Health Care Administration (Secretary), in conjunction with the State Surgeon General, are required to establish the policy workgroup composed of health care providers, patients who have experienced blood clots, family members of patients who have died from blood clots, advocates, and other interested parties and associations.

The workgroup is tasked with identifying specific background information pertaining to the prevalence, data collection, impacts, standards of care, and emerging treatments of blood clots and pulmonary embolisms. The workgroup is further tasked with developing a risk surveillance system for various health care providers and facilities and policy recommendations to improve patient awareness, including written materials and guidelines that affect the standard of care for patients at risk of forming blood clots.

The Secretary is directed to submit a final report detailing findings and recommendations to the Governor, the President of the Senate, and the Speaker of the House of Representatives by January 4, 2025.

The bill has no fiscal impact on state revenues or state expenditures.

The bill takes effect on July 1, 2023.

II. Present Situation:

A pulmonary embolism (PE) is a sudden blockage in a pulmonary artery resulting from a blood clot that develops in a blood vessel (often in the leg) that travels through the circulatory system to a lung, creating the blockage in blood flow.¹

The heart, arteries, capillaries, and veins make up the body's circulatory system. Blood is pumped with great force from the heart into the arteries. From there blood flows into the capillaries (tiny blood vessels in the tissues). Blood returns to the heart through the veins. As it moves through the veins back to the heart, blood flow slows. Sometimes this slower blood flow may lead to clot formation.

Blood clotting is a normal process to prevent bleeding. The body makes blood clots and then breaks them down. Under certain circumstances, the body may be unable to break down a clot. When blood clots in a vein, it may be due to the slowed blood flow, an abnormality in clot forming, or from an injury to the blood vessel wall.

Blood clots can form in arteries and veins. Clots formed in veins are called venous clots. Veins of the legs can be superficial veins (close to the surface of the skin) or deep veins (located near the bone and surrounded by muscle).

Venous clots most often happen in the deep veins of the legs. This is called deep vein thrombosis (DVT). Once a clot has formed in the deep veins of the leg, there is a potential for part of the clot to break off and travel through the blood to another area of the body, often the lung. DVT is the most common cause of a pulmonary embolism.

Other less frequent sources of pulmonary embolism are a fat embolus (often linked to the breaking of a large bone), amniotic fluid embolus, air bubbles, and a deep vein thrombosis in the upper body. Clots may also form on the end of an indwelling intravenous (IV) catheter, break off, and travel to the lungs.

Risk factors²

Although anyone can develop blood clots that result in a pulmonary embolism, certain factors can increase the risk.

- History of blood clots.
- Some medical conditions and treatments create higher risk, such as:
 - Heart disease. Heart and blood vessel disease, specifically heart failure, makes clot formation more likely.
 - Cancer. Certain cancers, especially brain, ovary, pancreas, colon, stomach, lung and kidney cancers, and cancers that have spread, can increase the risk of blood clots. Chemotherapy further increases the risk.

¹ Johns Hopkins Medicine, *Pulmonary Embolism*, available at <https://www.hopkinsmedicine.org/health/conditions-and-diseases/pulmonary-embolism> (last visited Mar. 22, 2023).

² Mayo Clinic, *Pulmonary embolism*, available at <https://www.mayoclinic.org/diseases-conditions/pulmonary-embolism/symptoms-causes/syc-20354647> (last visited Mar. 22, 2023).

- Surgery. Surgery is one of the leading causes of problem blood clots. For this reason, medicine to prevent clots may be given before and after major surgery, such as joint replacement.
- Disorders that affect clotting. Some inherited disorders affect blood, making it more likely to clot. Other medical disorders such as kidney disease also can increase the risk of blood clots.
- COVID-19. People who have severe symptoms of COVID-19 have an increased risk of pulmonary embolism.
- Blood clots are more likely to form during longer than usual periods of inactivity, such as:
 - Bed rest. Being confined to bed for an extended period after surgery, a heart attack, leg fracture, trauma, or any serious illness creates higher risk of blood clots.
 - Long trips. Sitting in a cramped position during lengthy plane or car trips slows blood flow in the legs, which increases the risk of blood clots.

Other risk factors

- Smoking. For reasons that aren't well understood, tobacco use increases the risk of blood clots in some people, especially those who have other risk factors.
- Being overweight. Excess weight increases the risk of blood clots – particularly in people with other risk factors.
- Supplemental estrogen. The estrogen in birth control pills and in hormone replacement therapy can increase clotting factors in the blood, especially in those who smoke or are overweight.
- Pregnancy. The weight of a baby pressing on veins in the pelvis can slow blood return from the legs. Clots are more likely to form when blood slows or pools.

Symptoms

Pulmonary embolism symptoms can vary greatly, depending on how much of the lung is involved, the size of the clots, and the existence of underlying lung or heart disease.

Common symptoms include:

- Shortness of breath. This symptom usually appears suddenly. Trouble catching one's breath happens even when resting and gets worse with physical activity.
- Chest pain. Afflicted persons might feel like they are having a heart attack. The pain is often sharp and felt when taking deep breaths.
- Fainting. An afflicted person may pass out if his or her heart rate or blood pressure drops suddenly. This is called syncope.

Other symptoms that can occur with pulmonary embolism include:

- A cough that may include bloody or blood-streaked mucus.
- Rapid or irregular heartbeat.
- Lightheadedness or dizziness.
- Excessive sweating.
- Fever.
- Leg pain or swelling, or both, usually in the back of the lower leg.
- Clammy or discolored skin, called cyanosis.

Treatment for pulmonary embolism³

Treatment choices for pulmonary embolism (PE) include:

- Anticoagulants. Also described as blood thinners, these medicines decrease the ability of the blood to clot. This helps stop a clot from getting bigger and keep new clots from forming.
- Fibrinolytic therapy. Also called clot busters, these medicines are given intravenously (IV or into a vein) to break down the clot. These medicines are only used in life-threatening situations.
- Vena cava filter. A small metal device placed in the vena cava (the large blood vessel that returns blood from the body to the heart) may be used to keep clots from traveling to the lungs. These filters are generally used when a person cannot tolerate anticoagulation treatment (for medical reasons), develops more clots even with anticoagulation treatment, or has bleeding problems from anticoagulation medicines.
- Pulmonary embolectomy. Rarely used, this is surgery is performed to remove a PE. It is generally done only in severe cases when a PE is very large, the patient cannot get anticoagulation and/or thrombolytic therapy due to other medical problems or he or she has not responded well to those treatments, or the patient's condition is unstable.
- Percutaneous thrombectomy. A long, thin, hollow tube (catheter) can be threaded through the blood vessel to the site of the embolism guided by X-ray. Once the catheter is in place, it is used to break up the embolism, pull it out, or dissolve it using thrombolytic medicine.

An important aspect of treating a PE is treatment to prevent formation of additional embolisms.

Task Force

A “workgroup” is not defined in the Florida Statutes. However, s. 20.03, F.S., includes definitions related to the required organizational structure of task forces. In part, it defines a “task force” as an advisory body created without specific statutory enactment for a time not to exceed one year or created by specific statutory enactment for a time not to exceed three years and appointed to study a specific problem and recommend a solution or policy alternative with respect to that problem. Its existence terminates upon the completion of its assignment.⁴

III. Effect of Proposed Changes:

Section 1 creates a non-statutory section of law citing the bill as the “Emily Adkins Prevention Act.”

Section 2 creates s. 408.0621, F.S., to establish the blood clot and pulmonary embolism policy workgroup. The Secretary of Health Care Administration (Secretary), in conjunction with the State Surgeon General, are required to establish the workgroup tasked with the following:

- Identifying the aggregate number of people who experience blood clots and pulmonary embolisms each year in this state.

³Johns Hopkins Medicine, *Pulmonary Embolism*, available at <https://www.hopkinsmedicine.org/health/conditions-and-diseases/pulmonary-embolism> (last visited Mar. 22, 2023).

⁴ Section 20.30(8). F.S.

- Identifying how data is collected regarding blood clots, pulmonary embolisms, and adverse health outcomes associated with these conditions.
- Identifying how blood clots and pulmonary embolisms impact the lives of people in this state.
- Identifying the standards of care for blood clot surveillance, detection, and treatment.
- Identifying emerging treatments, therapies, and research relating to blood clots.
- Developing a risk surveillance system to help health care providers identify patients who may be at higher risk of forming blood clots and pulmonary embolisms.
- Developing policy recommendations to help improve patient awareness of blood clot risks.
- Developing policy recommendations to help improve surveillance and detection of patients who may be at a higher risk of forming blood clots in licensed health care facilities, including, hospitals, nursing homes, assisted living facilities, residential treatment facilities, and ambulatory surgical centers.
- Developing policy recommendations relating to guidelines used that affect the standard of care for patients at risk of forming blood clots.
- Developing policy recommendations relating to providing patients and their families with written notice of increased risks of forming blood clots.

The bill requires the workgroup to be composed of health care providers, patients who have experienced blood clots, family members of patients who have died from blood clots, advocates, and other interested parties and associations.

The bill requires the President of the Senate and the Speaker of the House of Representative to each appoint two members to the workgroup and the State Surgeon General to appoint the chair of the workgroup. The bill authorizes the chair to create subcommittees to help with research, scheduling speakers on important subjects, and drafting a workgroup report and policy recommendations.

The bill authorizes meetings of the workgroup to be held through teleconference or other electronic means and prohibits workgroup members from being compensated.

The Secretary is required to submit a final report detailing the findings and recommendations to the Governor, the President of the Senate, and the Speaker of the House of Representatives by January 4, 2025.

Section 3 provides an effective date of July 1, 2023.

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:

None.

C. Government Sector Impact:

The bill has no fiscal impact on state revenues or state expenditures.⁵

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill creates section 408.0621 of the Florida Statutes.

This bill creates one non-statutory section of the Laws of Florida.

IX. Additional Information:

A. Committee Substitute – Statement of Changes:

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

CS by Health Policy on March 27, 2023:

⁵ Agency for Health Care Administration, HB 483 Bill Analysis (January 27, 2023) (on file with Senate Appropriations Committee on Health and Human Services).

The CS changes the citation for the Act to the “Emily Adkins Prevention Act” and establishes the workgroup in a newly created statute. The number of appointed members on the workgroup is reduced from 17 to five. The amendment is silent on reimbursement for per diem or travel expenses. The CS streamlines the responsibilities of the workgroup and focuses the policy recommendations on the risks of forming blood clots and early detection and prevention. The CS requires an annual report that includes detailed findings and recommendations rather than an update on the workgroup’s activities, findings, and recommendations. Submission of the final report is moved up from January 31, 2025, to January 4, 2025. The CS eliminates the sunset date for the workgroup included in the underlying bill.

B. Amendments:

None.