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 Health Policy

BILL:	SB 612
INTRODUCER:	Senator Yarborough
SUBJECT:	Prevention of Blood Clots
DATE:	March 24, 2023
REVISED:	

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Stovall	Brown	HP	**Pre-meeting**
2.			AHS	
3.			FP	

I. Summary:

SB 612 creates an interagency workgroup to address blood clot and embolism education, prevention, and treatment. The Agency for Health Care Administration (AHCA), in conjunction with the Department of Health (DOH), is tasked with administering the 17-member workgroup.

A preliminary report must be submitted to the Governor, the President of the Senate, and the Speaker of the House of Representatives by January 31, 2024, and a final report must be submitted by January 31, 2025. The enabling statute for the workgroup expires February 1, 2025.

The bill takes effect upon becoming a law.

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.

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

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 factors[2]

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

- History of blood clots**.**
- Medical conditions and treatments. 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.
  - 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.
- Extended periods of inactivity. 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.

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

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 embolism[3]

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

[3] *Supra* n 1.

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 Blood Clot Prevention Act."

Section 2 creates a non-statutory section of law establishing a blood clot and pulmonary embolism prevention policy workgroup. The AHCA, in conjunction with the DOH, is tasked with establishing the workgroup. The 17-member workgroup will include the following members:
- Four members representing state-licensed health care facilities, appointed by the Secretary of Health Care Administration.
- Four members representing state-licensed health care providers, appointed by the State Surgeon General. The Surgeon General will select one of his or her appointees to serve as chair of the workgroup.
- Five members representing patients who have experienced blood clots, family members of patients who have died from blood clots, advocates for blood clot and pulmonary embolism prevention policies, health care associations, and other interested parties or associations, appointed by the Governor.
- Two members appointed by the President of the Senate.
- Two members appointed by the Speaker of the House of Representatives.

Members of the workgroup are not entitled to receive compensation or reimbursement for per diem or travel expenses. The workgroup will meet at the call of the chair and may conduct its meetings through teleconference or other electronic means.

[4] Section 20.30(8). F.S.

The chair may create subcommittees to help with gathering research, scheduling speakers on relevant subjects, and drafting workgroup reports and policy recommendations.

At a minimum, the workgroup will:

- Identify the aggregate number of people who experience blood clots and pulmonary embolisms each year in this state.
- Identify how data is collected in this state regarding blood clots, pulmonary embolisms, and adverse health outcomes associated with these conditions.
- Identify how blood clots and pulmonary embolisms impact the lives of residents in this state.
- Identify the best practices and standards of care for blood clot surveillance, detection, and treatment.
- Identify emerging treatments, therapies, and research relating to blood clots and pulmonary embolisms.
- Develop a risk surveillance system to help health care providers identify patients who may be at higher risk for blood clots or pulmonary embolisms.
- Develop policy recommendations to help improve patient awareness of blood clot risks.
- Develop policy recommendations to help health care facilities, including, but not limited to, hospitals, ambulatory surgical centers, nursing homes, assisted living facilities, and residential treatment facilities, improve surveillance and detection of patients who may be at a higher risk for blood clots or pulmonary embolisms.
- Develop recommended guidelines for the standard of care for patients at risk for blood clots or pulmonary embolisms.
- Develop recommended literature relating to increased risks of blood clots which health care facilities and health care providers can provide to patients and their families.

The AHCA is required to submit a report updating the Governor, the President of the Senate, and the Speaker of the House of Representatives on the workgroup's activities, findings, and recommendations by January 31, 2024. The AHCA must submit a final report on all of the workgroup's findings and recommendations by January 31, 2025.

Authorization for the workgroup expires February 1, 2025.

The bill takes effect upon becoming a law.

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 AHCA and the DOH will incur insignificant costs to coordinate and manage the workgroup and for preparing the interim and final reports.

VI. Technical Deficiencies:

None.

VII. Related Issues:

The bill creates a non-statutory section of law for this workgroup that will exist for more than one year, if enacted. If the workgroup is deemed to be a task force, s. 20.03, F.S., requires statutory authorization for a task force to exist in excess of one year.

VIII. Statutes Affected:

This bill creates two non-statutory sections 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.)

None.

B. Amendments:

None.