Public Health Committee
JOINT FAVORABLE REPORT

Bill No.: HB-6836
Title: AN ACT CONCERNING BLOOD PLASMA COLLECTION.
Vote Date: 3/27/2023
Vote Action: Joint Favorable Substitute
PH Date: 3/6/2023
File No.:

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SPONSORS OF BILL:

The Public Health Committee.

REASONS FOR BILL:

Plasma-derived therapies are a vital component in treating people with rare and complex diseases such as hemophilia and many autoimmune conditions. Starting October 1, 2023, this bill creates a new licensure category for plasma donation centers and blood collection facilities. Any person or business is prohibited from conducting, operating or maintaining such an entity without obtaining this new license from the Department of Public Health (DPH). The bill also establishes the following new licensure requirements:

- Increases from $200 to $650, the initial and renewal license fees for clinical laboratories, blood collection facilities and source plasma donation centers.
- Requires DPH to conduct necessary inspections and/or investigations of any facility for blood donation or source plasma donation that is applying for licensure.
- Authorizes DPH to exercise disciplinary action against any facility or center found to be engaging in fraudulent practices, fee-splitting inducements, bribes or violating state laws or regulations.
- Prohibits the termination of any employee of these facilities or donation centers for reporting to DPH any violation of applicable state laws and/or regulations.
- Requires DPH to adopt regulations implementing this new licensure category provided the policies and procedures are posted on the e-Regulations System before they are adopted.

RESPONSE FROM ADMINISTRATION/AGENCY:

Manisha Juthani, MD, Commissioner of the DPH:
DPH appreciates and acknowledges that most of the language in this bill is also proposed by DPH in the department's bill HB 6733. However, the department takes issue with new language in lines 171-176 that would require DPH to grant waivers prior to licensure. Such action carries serious concerns for the health and safety of the public. In this proposal a facility only needs to abide by federal regulation 21 CFR 630. The focus of this regulation is only on the eligibility of a donor with no mention of the health and safety requirements of a physical plant. The DPH understands that several providers are eager to begin services in our state and that is why DPH proposed the language in its bill HB 6733. She notes that DPH is currently working diligently with several licensed laboratories to grant waivers which are expected to be issued in the coming weeks.

Representative Jack Fazzino, 83rd Assembly District, CGA:
Rep. Fazzino points out that rare degenerative and autoimmune diseases affect more than 300,000 Connecticut residents. Expanding plasma donation in our state could be life changing for those afflicted. Expansion of this service also has economic benefits as it is an untapped market that would create jobs and bring capital investment to our state. Although this economic impact is a benefit, the most important aspect of this legislation is the added health and safety for Connecticut residents. To facilitate prompt and effective implementation, Rep. Fazzino, requests that the Committee consider amending Subsection (k) to allow the DPH some flexibility in granting waivers for blood plasma collection.

NATURE AND SOURCES OF SUPPORT:

Eva Quinley, Senior Director, Regulatory Affairs, CSL Plasma:
The passage last year of HB 5500 provided the DPH with waiver authority for regulations related to clinical laboratories. When this bill was signed into law, CSL began to build a plasma center in Manchester CT. It was the intent of CSL to open this center months ago bringing with it not only this critical service, but the accompanying employment and economic impact to the area. We unfortunately learned from DPH that we would not be eligible for waivers until after licensure. This placed great uncertainty on this project. The language in this bill addresses our concern by providing the Commissioner the authority to grant waivers prior to licensing provided the centers comply with 21 CFR 630. The retention of this language is critical to CSL Plasma.

Christine Kennedy Specialty Sales Representative, GRIFOLS:
Grifols is a global healthcare company that has enhanced the health and well-being of people around the world since 1909. Grifols does not currently operate any plasma donor centers in Connecticut due to outdated regulations. Grifols supports this legislation that will allow the Connecticut DPH to establish updated regulations that will govern source plasma donor centers. Ms. Kennedy specifically encourages the DPH to establish an expedited timeline that would allow the department to grant a waiver for plasma collection centers prior to licensure.

Bernadette West, MD, Regional Director and Mario Bruno, Regional Executive, American Red Cross:
The Red Cross fully supports this bill and would like to reinforce that it does not affect donor or patient safety. Although blood collection is performed safely across the country following FDA regulations and Association for the Advancement of Blood & Biotherapies (AABB) standards, it is important to note that Connecticut regulations are more stringent than the FDA and AABB requirements. By approving this bill, the DPH will evaluate and update existing regulations ultimately allowing for increased blood collection within our state while assuring donor safety.

Ryan Seidel, Head of Market Expansion and Business Development, Bio Life-Plasma Derived Therapies, Takeda Pharmaceutical Company:
Mr. Seidel points out that plasma-derived therapies can only be produced using human plasma. Enabling a sustainable supply of plasma to meet the growing patient demand for these therapies is crucial. Takeda appreciates the Committee's recommendation to rely on federal source plasma donation regulations as the basis for governing this process during the waiver process until regulations, policies and procedures are adopted. This would address an inconsistency in the current statute which has been interpreted to only allow waivers for centers already licensed in Connecticut.

Testimony in support of this bill was also submitted by:
Lesley Bennett, CT-Rare Action Network State Ambassador
Bill Speir, Se3nior Director, State Affairs, Plasma Protein Therapeutics Association
Lisa Butler, Executive Director, GBS/CIDP Foundation International
Matthew Prentice, Director of State Policy, Immune Deficiency Foundation
Betsy Jett, Senior VP, Quality and Regulatory Affairs, New York Blood Center
Thomas Lilburn, resident of Madison, Former Pharmaceutical Representee

NATURE AND SOURCES OF OPPOSITION:

Connecticut Hospital Association (CHA):
CHA opposes the bill as written as it would cause confusion and disruption in a hospital's use and collection of blood products. The confusion centers around which licenses are needed to be blood collection facilities or plasma donation centers. Since CHA believes this bill will likely cause blood supply disruptions across the state, we urge the following two changes:

- Add a clause that states "nothing herein affects the ability of a licensed hospital to undertake any blood collection processes that are consistent with federal law"
- Modify or delete lines 170-176. The language in this section should be drafted to provide clarity so as not to impede the availability of blood products in Connecticut.

Mary Krusiewicz, RN, Vice President of AFSCME Local 3145 representing Red Cross workers in CT:
Ms. Krusiewicz points out that there is a big difference between simple blood collection and Apheresis which is the process used to collect plasma. During Apheresis the donor must be infused with a saline solution and an anticoagulant. Currently, the DPH regulations require that the infusion of these, and any solutions be performed only by licensed personnel. There was discussion in the past to eliminate certain regulations which would allow for the lowering of staff qualifications for performing Apheresis. Such a move was rejected by this Committee in the past. With this bill the Commissioner could potentially eliminate the requirement for an

MD on sight as well as the requirement for licensed RN's/LPNs. This bill eliminates important protections of the public that DPH can currently execute. The plasma industry has surged and is now a multi-billion-dollar industry and strong oversight must remain strong to protect the safety of donors.

Linda Dalessio, Taxpayer:
The Commissioner is not law enforcement nor an elected official. Commissioners have no jurisdiction to issue subpoenas or conduct law enforcement. This is a clear violation of government and constitutes overreach into health care issues.

Reported by: Kathleen Panazza **Date: April 5, 2023**