House of Representatives

General Assembly

File No. 587

January Session, 2023

Substitute House Bill No. 6836

House of Representatives, April 13, 2023

The Committee on Public Health reported through REP. MCCARTHY VAHEY of the 133rd Dist., Chairperson of the Committee on the part of the House, that the substitute bill ought to pass.

AN ACT CONCERNING BLOOD PLASMA COLLECTION.

Be it enacted by the Senate and House of Representatives in General Assembly convened:

Section 1. Section 19a-565 of the general statutes is repealed and the following is substituted in lieu thereof (*Effective October 1, 2023*):

(a) As used in this section: **[**, "clinical laboratory"**]**

(1) "Blood collection facility" means a facility that performs blood component collection activities where blood is removed from a human being for the purpose of administering such blood or any of its components to any human being. "Blood collection facility" does not include a facility that performs blood component collection activities to collect source plasma or perform testing that would require licensure as a clinical laboratory;

(2) "Business entity" means a corporation, association, trust, estate, partnership, limited partnership, limited liability partnership, limited

liability company, sole proprietorship, joint stock company, nonstock corporation, John Dempsey Hospital and The University of Connecticut Health Center;

(3) "Clinical laboratory" has the same meaning as provided in section 19a-490;

(4) "Plasmapheresis" means a procedure in which blood is removed from a blood donor, the plasma is separated from the formed elements and at least the red blood cells are returned to the blood donor at the time of the donation;

(5) "Source plasma" means the liquid portion of human blood collected by plasmapheresis and intended as source material for further manufacturing use. "Source plasma" does not include single donor plasma products intended for intravenous use; and

(6) "Source plasma donation center" means a facility where source plasma is collected by plasmapheresis.

(b) The Department of Public Health shall adopt regulations, in accordance with the provisions of chapter 54, **[**to establish reasonable standards governing exemptions from the licensing provisions of this section,**]** governing clinical laboratories, blood collection facilities and source plasma donation centers. Such regulations shall establish reasonable standards for entities exempt from licensure as a clinical laboratory, operations and facilities, personnel qualifications and certification, levels of acceptable proficiency in testing programs approved by the department, the collection, acceptance and suitability of specimens for analysis and such other pertinent laboratory functions, including the establishment of advisory committees, as may be necessary to **[**insure**]** ensure public health and safety. The Commissioner of Public Health may implement policies and procedures necessary to administer the provisions of this section while in the process of adopting such policies and procedures as regulations, provided the department posts such policies and procedures on the eRegulations System prior to adopting them. Policies and procedures implemented pursuant to this

section shall be valid until final regulations are adopted in accordance with the provisions of chapter 54.

(c) No person **[**, firm or corporation**]** or business entity shall establish, conduct, operate or maintain a clinical laboratory, blood collection facility or source plasma donation center unless such laboratory, facility or center is licensed or approved by said department in accordance with its regulations. Each blood collection facility or plasmapheresis center, as defined in section 19a-36-A47 of the regulations of Connecticut state agencies, that is registered with the department on or before October 1, 2023, shall apply to the department for an initial license pursuant to the provisions of this section not later than thirty days after the date that procedures for such licensure are implemented by the department pursuant to subsection (b) of this section. On and after the date on which procedures for licensure are implemented by the department pursuant to the provisions of said subsection, the department shall not renew any blood collection facility or plasmapheresis center registration. Each clinical laboratory, blood collection facility or source plasma donation center shall comply with all standards for **[**clinical laboratories**]** such facilities established by the department and shall be subject to inspection by said department, including inspection of all records necessary to carry out the purposes of this section. **[**The commissioner, or an agent authorized by the commissioner, may conduct any inquiry, investigation or hearing necessary to enforce the provisions of this section or regulations adopted under this section and shall have power to issue subpoenas, order the production of books, records or documents, administer oaths and take testimony under oath relative to the matter of such inquiry, investigation or hearing. At any such hearing ordered by the department, the commissioner or such agent may subpoena witnesses and require the production of records, papers and documents pertinent to such hearing. If any person disobeys such subpoena or, having appeared in obedience thereto, refuses to answer any pertinent question put to such person by the commissioner or such agent or to produce any records and papers pursuant to the subpoena, the commissioner or such agent may apply to the superior court for the judicial district of Hartford or for the judicial district wherein the person

resides or wherein the business has been conducted, setting forth such disobedience or refusal and said court shall cite such person to appear before said court to answer such question or to produce such records and papers.**]**

[(c)**]** (d) Each initial or renewal application for licensure of a clinical laboratory, **[**if such laboratory is located within an institution licensed in accordance with sections 19a-490 to 19a-503, inclusive, shall be made on forms provided by said department**]** blood collection facility or source plasma donation center shall be made in a form and manner prescribed by the commissioner and shall be executed by the owner or owners or by a responsible officer of the firm or corporation owning **[**the**]** such laboratory, **[**. Such application shall contain a current itemized rate schedule, full disclosure of any contractual relationship, written or oral, with any practitioner using the services of the laboratory and such other information as said department requires, which may include affirmative evidence of ability to comply with the standards as well as a sworn agreement to abide by them. Upon receipt of any such application, said department shall make such inspections and investigations as are necessary and shall deny licensure when operation of the clinical laboratory would be prejudicial to the health of the public. Licensure shall not be in force until notice of its effective date and term has been sent to the applicant.**]** facility or donation center and be accompanied by the fee required pursuant to the provisions of subsection (f) of this section. A mobile or temporary blood collection facility shall not be required to obtain a license if such person or business entity operating such facility is licensed as a blood collection facility.

(e) After the department receives an initial or renewal application for licensure pursuant to subsection (d) of this section, it shall conduct any inspections or investigations that are deemed necessary by the commissioner to determine the applicant's eligibility for licensure. As a condition of licensure, the commissioner may require the applicant to sign a consent order providing reasonable assurances of compliance with federal and state laws and regulations. The commissioner may deny licensure of an applicant if the commissioner determines that the

applicant has previously failed to comply with federal and state laws and regulations or that licensure would pose a threat to the health, safety and well-being of the public. Licensure pursuant to the provisions of this section shall not be effective until the applicant receives notice of such licensure, including the effective date and term of such licensure, from the department.

[(d)**]** (f) A nonrefundable fee of **[**two**]** six hundred fifty dollars shall accompany each application for a license or for renewal thereof, except in the case of a clinical laboratory owned and operated by a municipality, the state, the United States or any agency of said municipality, state or United States. Each license shall be issued for a period of not less than twenty-four **[**nor more than twenty-seven**]** months. **[**from the deadline for applications established by the commissioner.**]** Renewal applications shall be made **[**(1)**]** biennially within the **[**twenty-fourth**]** twentieth month of the current license. **[**; (2) before any change in ownership or change in director is made; and (3) prior to any major expansion or alteration in quarters.**]** Any change in ownership of a business entity licensed pursuant to the provisions of this section shall be made in compliance with section 19a-493. If any such business entity changes its director, it shall notify the commissioner in a form and manner prescribed by the commissioner. If any such business entity intends to expand or alter its facility, it shall notify the commissioner in a form and manner prescribed by the commissioner prior to such expansion or alteration. The licensed clinical laboratory shall report to the Department of Public Health, in a form and manner prescribed by the commissioner, the name and address of each **[**blood**]** specimen collection facility owned and operated by the clinical laboratory, prior to the issuance of a new license, prior to the issuance of a renewal license or whenever a **[**blood**]** specimen collection facility opens or closes.

[(e)**]** (g) A license issued under this section may be revoked or suspended in accordance with chapter 54 or subject to any other disciplinary action specified in section 19a-17 if **[**such**]** the licensed clinical laboratory, blood collection facility or source plasma donation

center has engaged in fraudulent practices, fee-splitting inducements or bribes, including, but not limited to, in the case of a clinical laboratory, violations of subsection [(f)] (h) of this section, or violated any other provision of this section or regulations adopted under this section after notice and a hearing is provided in accordance with the provisions of said chapter.

[(f)] (h) No representative or agent of a clinical laboratory shall solicit referral of specimens to his or any other clinical laboratory in a manner which offers or implies an offer of fee-splitting inducements to persons submitting or referring specimens, including inducements through rebates, fee schedules, billing methods, personal solicitation or payment to the practitioner for consultation or assistance or for scientific, clerical or janitorial services.

[(g)] (i) No clinical laboratory, blood collection facility or source plasma donation center shall terminate the employment of an employee because such employee reported a violation of this section to the Department of Public Health.

[(h)] (j) Any person [, firm or corporation] or business entity operating a clinical laboratory, blood collection facility or source plasma donation center in violation of this section shall be fined not less than one hundred dollars or more than three hundred dollars for each offense. For purposes of calculating civil penalties under this section, each day a licensee operates in violation of this section or a regulation adopted under this section shall constitute a separate violation.

[(i)] (k) The Commissioner of Public Health shall adopt regulations in accordance with the provisions of chapter 54 to establish levels of acceptable proficiency to be demonstrated in testing programs approved by the department for those laboratory tests which are not performed in a licensed clinical laboratory. Such levels of acceptable proficiency shall be determined on the basis of the volume or the complexity of the examinations performed.

This act shall take effect as follows and shall amend the following sections:		
Section 1	*October 1, 2023*	19a-565

Statement of Legislative Commissioners:

In Subsec. (d), "blood collection facility or source plasma donation center" was inserted after "clinical laboratory," for consistency with other provisions of the Subsec.; and in Subsec. (f), "entity" was changed to "business entity", for consistency with Subsec. (a)(2).

PH *Joint Favorable Subst.*

The following Fiscal Impact Statement and Bill Analysis are prepared for the benefit of the members of the General Assembly, solely for purposes of information, summarization and explanation and do not represent the intent of the General Assembly or either chamber thereof for any purpose. In general, fiscal impacts are based upon a variety of informational sources, including the analyst's professional knowledge. Whenever applicable, agency data is consulted as part of the analysis, however final products do not necessarily reflect an assessment from any specific department.

OFA Fiscal Note

State Impact:

Agency Affected	Fund-Effect	FY 24 $	FY 25 $
Resources of the General Fund	GF - Revenue Gain	61,650	68,400
Resources of the General Fund	GF - Revenue Gain	See Below	See Below

Note: GF=General Fund

Municipal Impact: None

Explanation

The bill results in a General Fund revenue gain of $61,650 in FY 24 and $68,400 in FY 25 by increasing, from $200 to $650, the initial and renewal license fees for clinical laboratories.[1] This bill also creates new Department of Public Health (DPH) licensure categories for blood collection facilities and source plasma donation centers, starting 10/1/23, with initial and renewal license fees of $650. The revenue gain to the General Fund from the new licensure categories will be dependent upon the number of initial and renewal licenses issued by DPH.

The Out Years

The annualized ongoing fiscal impact identified above would continue into the future subject to subject to the number of initial and renewal licenses issued by DPH.

[1]There are 137 clinical laboratories whose licenses renew in the even years and 152 clinical laboratories whose licenses renew in the odd years.

OLR Bill Analysis
sHB 6836

AN ACT CONCERNING BLOOD PLASMA COLLECTION.

SUMMARY

This bill creates new Department of Public Health (DPH) licensure categories for blood collection facilities and source plasma donation centers and establishes related licensure requirements. (Under current practice, these facilities and centers must register with DPH and comply with federal and state laws and regulations for clinical laboratories.)

Starting October 1, 2023, the bill prohibits a person or business (e.g., corporation, partnership, limited liability company, John Dempsey Hospital, UConn Health Center) from conducting, operating, or maintaining a center or facility unless it obtains the new DPH license. It establishes an initial and renewal license fee of $650 and requires licenses to be renewed every two years.

It requires the DPH commissioner to adopt regulations to implement the new licenses and allows her to implement policies and procedures while doing so if she posts the policies and procedures on the eRegulations system before adopting them. The policies and procedures are valid until the final regulations are adopted.

The bill also modifies licensure requirements for clinical laboratories by (1) increasing, from $200 to $650, the initial and renewal license fee and (2) modifying the information that must be included on licensure applications.

Lastly, the bill makes technical and conforming changes.

EFFECTIVE DATE: October 1, 2023

LICENSURE REQUIREMENTS

Definitions

Under the bill, a "blood collection facility" is a facility that performs blood component collection activities where blood is removed from a person to administer the blood, or its components, to another person. It excludes facilities that perform these activities to collect source plasma or perform testing that requires a clinical laboratory license.

A "source plasma donation center" is a facility where source plasma is collected by plasmapheresis, which is a procedure that separates plasma from blood removed from a donor and then returns the red blood cells to the donor at the time of donation. "Source plasma" is the liquid part of human blood collected by plasmapheresis for use as source material for further manufacturing use. It does not include single donor plasma products for intravenous use.

License Applications

The bill requires blood collection facilities and plasmapheresis centers (now called "source plasma donation centers") registered with DPH on or before October 1, 2023, to apply to DPH for an initial license within 30 days after DPH implements licensure procedures.

Starting on this implementation date, the bill prohibits DPH from renewing blood collection facility or plasmapheresis registrations, instead requiring them to obtain the new license. The owner or responsible officer of the facility or center must apply for the license as the commissioner prescribes. However, a mobile or temporary blood collection facility is not required to obtain a license if its operator is licensed as a blood collection facility.

For clinical laboratories, the bill eliminates current law's requirement that licensure applications contain (1) an itemized rate schedule, (2) full disclosure of any written or oral contractual relationship with a practitioner using the laboratory's services, and (3) any other information DPH requires.

License Renewals and Fees

The bill generally increases, from $200 to $650, the initial and renewal license fees for clinical laboratories and extends the same fees to blood collection facilities and source plasma donation centers. (By law, clinical laboratories owned and operated by a government agency are exempt from licensure fees.)

Under current law, a clinical laboratory must apply to renew its license (1) every two years during the 24th month, (2) before any change in owner or director, and (3) before any major expansion or change in quarters.

The bill instead requires a clinical laboratory to biennially apply to renew its license during the 20th month. For a change in ownership, DPH must first inspect the facility and approve the change. If the laboratory changes its director or intends to expand or alter its facility, it must first notify the DPH commissioner in a form and manner she determines. The bill extends these same requirements to blood collection facilities and source plasma donation centers.

Inspections and Investigation

Under the bill, blood collection facilities and plasma donation centers are subject to DPH inspections, including any necessary records inspection, as existing law requires for clinical laboratories. Once DPH receives an initial or renewal license application for a blood collection facility or source plasma donation center, DPH must conduct any inspections or investigations the commissioner finds necessary to determine an applicant's eligibility licensure eligibility.

The bill permits the DPH commissioner to require an applicant to sign a consent order providing reasonable assurance the applicant will comply with federal and state laws and regulations. The commissioner may deny an application if she determines the applicant previously failed to comply with the laws or that licensure would threaten the public's health, safety, and well-being, as she may already do for clinical laboratories.

A license is not effective until the applicant receives a notice of

licensure from DPH, including its effective date and terms.

Disciplinary Action

The bill authorizes the DPH commissioner to take various disciplinary actions (e.g., license suspension or revocation or probation) against a blood collection facility or source plasma donation center after notice and a hearing. The commissioner may do this if the facility or center (1) engaged in fraudulent practices, fee-splitting inducements, or bribes or (2) violated applicable state laws and regulations. It subjects violators to a fine of between $100 and $300 for each offense.

Existing law already allows the commissioner to take disciplinary action and impose fines against a clinical laboratory in a similar manner.

Whistleblower Protection

The bill prohibits blood collection facilities and source plasma donation centers from terminating an employee because the employee reported to DPH that the facility or center violated state licensure law or regulation. This prohibition already applies to clinical laboratories.

BACKGROUND

Related Bill

HB 6733, favorably reported by the Public Health Committee, contains identical provisions creating new licensure categories for source plasma donation centers and blood collection facilities.

COMMITTEE ACTION

Public Health Committee

Joint Favorable Substitute
Yea 26 Nay 11 (03/27/2023)