General Assembly

Raised Bill No. 6836

January Session, 2023

LCO No. **4866**

Referred to Committee on PUBLIC HEALTH

Introduced by:
(PH)

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 Section 19a-565 of the general statutes is repealed and the following is substituted in lieu thereof (*Effective October 1, 2023*):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, clinical laboratory**]** 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 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**]** 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 an entity licensed pursuant to the provisions of this section shall be made in compliance with section 19a-493. If any such entity changes its director, it shall notify the commissioner in a form and manner prescribed by the commissioner. If any such 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.

(k) The commissioner shall grant a waiver pursuant to subsection (c) of section 19a-495 to a clinical laboratory to conduct blood plasma collection prior to such laboratory being licensed pursuant to the provisions of this section if such laboratory complies with the provisions of 21 CFR 630, as amended from time to time. Such waiver shall be in effect until the commissioner adopts policies and procedures pursuant to subsection (b) of this section.

[(i)**]** (l) 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 Purpose:

To require the Commissioner of Public Health to grant a waiver to clinical laboratories to conduct blood plasma collection prior to licensure.

[Proposed deletions are enclosed in brackets. Proposed additions are indicated by underline, except that when the entire text of a bill or resolution or a section of a bill or resolution is new, it is not underlined.]