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)