HOUSE BILL REPORT
SHB 2580

As Amended by the Senate

Title: An act relating to establishing a public registry for the transparency of blood establishments.

Brief Description: Establishing a public registry for the transparency of blood establishments.

Sponsors: House Committee on Health Care & Wellness (originally sponsored by Representatives Cody, Rodne, Robinson, Johnson and Jinkins).

Brief History:
Committee Activity:
Health Care & Wellness: 1/22/16, 2/3/16 [DPS].
Floor Activity:
Passed House: 2/17/16, 98-0.
Senate Amended.
Passed Senate: 3/2/16, 47-0.

Brief Summary of Substitute Bill

- Requires blood-collecting or distributing establishments (blood establishments) to register with the Department of Health (Department).
- Directs the Department to create and maintain an online registry of blood establishments.

HOUSE COMMITTEE ON HEALTH CARE & WELLNESS

Majority Report: The substitute bill be substituted therefor and the substitute bill do pass. Signed by 15 members: Representatives Cody, Chair; Riccelli, Vice Chair; Schmick, Ranking Minority Member; Harris, Assistant Ranking Minority Member; Caldier, Clibborn, DeBolt, Jinkins, Johnson, Moeller, Robinson, Rodne, Short, Tharinger and Van De Wege.

Staff: Chris Blake (786-7392).

Background:

This analysis was prepared by non-partisan legislative staff for the use of legislative members in their deliberations. This analysis is not a part of the legislation nor does it constitute a statement of legislative intent.

The federal Food and Drug Administration (FDA) requires that an entity obtain a biologics license prior to introducing, or delivering for introduction, a biological product into interstate commerce. Biological products include blood and blood components intended for transfusion or for further manufacture into injectable products. An entity that holds a biologics license must comply with FDA standards, including standards for personnel, work rooms, equipment, laboratories, records maintenance, and retention of samples. For a license holder that manufactures blood and blood components, there are more specific standards that must be met that include registration with the FDA.

In addition to obtaining a biologics license from the FDA, a blood establishment must be licensed with the Department of Health as a medical test site. A medical test site includes any facility or site that analyzes materials from the human body for the purposes of health care, treatment, or screening. To become licensed, a medical test site must demonstrate the ability to comply with applicable standards related to the accuracy of testing, staffing requirements, recordkeeping, quality assurance, and quality control.

Summary of Substitute Bill:

"Blood-collecting or distributing establishments" (blood establishments) are defined as organizations that collect or distribute blood for allogeneic transfusion in Washington. Hospitals are excluded from the definition unless the hospital is required to be licensed by the federal Food and Drug Administration (FDA) or conducts activities that would require an FDA license if conducted across state lines.

Blood establishments may not collect or distribute blood for transfusion in Washington unless they are registered with the Department of Health (Department). To become registered, a blood establishment must hold a license issued by the FDA and submit an application and fee to the Department. The application must include:

- the name and contact information for the blood establishment;
- a copy of the blood establishment's FDA license, unless the applicant is a hospital that is not required to be licensed by the FDA;
- a list of the blood establishment's clients in Washington;
- any titled letters, fines, or license suspensions issued by the FDA in the two years prior to application;
- any judicial consent decrees issued in the two years prior to application; and
- other information required by the Department.

The registration must be renewed annually through the submission of updated application information. A blood establishment must notify the Department within 14 days of the termination of a blood establishment's FDA license. The Department must deny or revoke the registration of any blood establishment that ceases to be licensed by the FDA. The Department may also seek an injunction against an entity that is collecting or distributing blood without a registration.

The Department must maintain an online public registry of all registered blood establishments that supply blood for transfusion in Washington, including all clients that each serves. The Department must update the registry within two weeks of receiving application-related information from a blood establishment, including any FDA or judicial action against

its FDA license and any change in client lists. The Department must notify all clients of a blood establishment within two weeks of being notified that it has had an FDA or judicial action against its FDA license or if it no longer holds an FDA license.

Legislative findings are made regarding the need to maintain public confidence in the safety of the community blood supply. The stated intent of the Legislature is that the registration of blood establishments ensure public transparency.

EFFECT OF SENATE AMENDMENT(S):

The Senate amendment eliminates the requirement that a hospital be registered by the state as a blood-collecting or distributing establishment if it is required to be licensed by the federal Food and Drug Administration (FDA) as a blood establishment or conducts activities in Washington that would require an FDA license if they were to be conducted in multiple states and, instead, applies the state registration requirement to hospitals that collect blood directly from donors for the purpose of allogeneic transfusions.

The Senate amendment exempts a blood-collection or distributing establishment from registration in cases in which a qualified provider determines that there is an individual patient medical need.

The Senate amendment removes the requirement that the online public registry of blood-collecting or distributing establishments include all of the clients served.

Appropriation: None.

Fiscal Note: Available.

Effective Date: The bill takes effect 90 days after adjournment of the session in which the bill is passed.

Staff Summary of Public Testimony:

(In support) This bill will further public confidence in the safety of the blood supply. It is difficult to find information on the federal Food and Drug Administration's oversight. Donors, patients, and the public should be able to easily access information about how blood establishments are doing and who their clients are. This bill will provide timely information to the public and blood purchasers in Washington. This bill is a step forward in assuring transparency. Not everyone has access to information about the safety of the blood supply.

(Opposed) None.

Persons Testifying: Representative Cody, prime sponsor; and Jim AuBuchon, Nancy Osborne, and Lisa Thatcher, Bloodworks Northwest.

Persons Signed In To Testify But Not Testifying: None.